IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
FORT WORTH DIVISION

STATE OF TEXAS and STATE OF OKLAHOMA , Plaintiffs, v. EMANUEL McCRAY, on behalf of himself and all other similarly situated, Intervenor Plaintiff, v. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al., Defendants.	Civ. A. No. 4:23-cv-00066-Y

BRIEF IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS PLAINTIFFS' COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

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I. Introduction

Seeking to protect millions of individuals from the spread of a communicable disease, Defendant Health and Human Services (HHS) considered a plethora of scientific data both here and abroad when determining its response to the 2019 coronavirus disease (COVID-19). COVID-19 is an easily transmissible, communicable disease that did not originate in the United States but rather migrated across the world, killing millions. Identifying, tracking, and analyzing the nature and scope of the pandemic was an international effort. The federal government had previously promulgated regulations to respond to pandemics generally. Federal regulations prescribed regulatory definitions of the term "public health emergency" and specified various steps that could be taken to protect residents from transmission of a communicable disease through quarantine measures.

Now, the States of Texas and Oklahoma (collectively, States) have demanded a new rulemaking, contending that the federal regulation, codified at 42 C.F.R. § 70.1 (§ 70.1), defining the phrase "public health emergency" as it relates to the isolation and quarantine of individuals is unlawful and/or unconstitutional. The States argue that some of the definitions, by referring to international guidelines issued by organizations like the World Health Organization (WHO), unlawfully delegate public-health decisions to foreign nationals or international organizations and "potentially" permit the federal government to encroach on the property or person of the States' populations. (Doc. 1, ¶ 21.) The States object to three definitions of a public health emergency (§ 70.1(3)-(5)) that refer to the World Health Organization's (WHO) (collectively, three definitions).

The States seek declaratory and injunctive relief against the "unlawful" three definitions of a communicable disease event.

The States' claims should be dismissed, however, because the States lack standing to bring these claims under the Administrative Procedure Act (APA). The States have identified no current or certainly impending injury that would be remedied by the requested rulemaking. The challenged definitions, by their very nature and in this context, identify an existing circumstance and operate as a predicate to action. But none of the definitions (including the three definitions) prescribe that HHS or the Centers for Disease Control and Prevention (CDC) take a certain action. Rather, other statutes and regulations authorize actions, not the regulatory definitions. Nor have the States identified any harm or a substantial risk of harm from the three definitions, as they must, to establish standing to sue the government. Any dispute is not ripe because Plaintiffs' claims are entirely speculative and based on the premise that HHS may take some action in response to a future pandemic. And even if the States had identified a justiciable controversy, the States cannot show that HHS's decision not to initiate a new rulemaking was arbitrary or capricious in violation of the APA. Defendants move to dismiss all claims for lack of subject matter jurisdiction under Federal Rule of Civil Procedure 12(b)(1) or 12(b)(6).

II. Background

Section 361 of the Public Health Service Act of 1944 ("PHSA") authorizes HHS "to make and enforce such regulations as in [the Secretary's] judgment are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign

countries into the States or possessions, or from one State or possession into any other State or possession."[1] 42 U.S.C. § 264(a). The CDC Director implements this authority through regulations at 42 C.F.R. part 70 (interstate) and part 71 (foreign) and permits the CDC to act when state or local control is inadequate. *See* Control of Communicable Diseases, 82 Fed. Reg. 6890, 6892 (Jan. 17, 2017); 42 C.F.R. § 70.2. If a public health emergency exists, HHS is statutorily permitted to isolate and examine individuals moving or about to move from one U.S. State into another and "reasonably believed to be infected with a communicable disease in a qualifying stage" in order to prevent the spread of communicable disease within the United States. 42 U.S.C. § 264(d).

A. HHS proposes five definitions of a "public health emergency," three of which refer to determinations made by the WHO or WHO officials.

In August 2016, HHS published a Notice of Proposed Rulemaking (81 FR 53240), proposing new definitions of the term "public health emergency" as used in Part 70 of Title 42, which is related to interstate quarantine in the public health context. (Doc. 1-3, at 2.) HHS felt it was important to define "public health emergency" as used under section 361(d)(2) to provide the public with a clear understanding of HHS/CDC's authority for interstate quarantine, isolation or conditional release. (Doc. 1-3 at 2.)

Two subsections of the proposed rule would define "public health emergency" to

[1] Although the statute assigns this authority to the Surgeon General, Reorganization Plan No. 3 of 1966 transferred all statutory powers and functions from the Surgeon General to the Secretary of Health, Education, and Welfare, now the Secretary of Health and Human Services, 31 Fed. Reg. 8855, 80 Stat. 1610 (June 25, 1966), *see also* An Act to Establish a Dep't of Educ., Pub. L. No. 96-88, § 509, 93 Stat. 695 (October 17, 1979) (codified at 20 U.S.C. 3508(b)). Although the Office of the Surgeon General was later re-established, the Secretary retains these authorities.

include a communicable disease event determined by the Director of the CDC or the Secretary of HHS, respectively. 42 C.F.R. § 70.1(1)-(2). The last three subsections define "public health emergency" to mean a communicable disease event that is notified to an international organization (WHO), is determined by the Director-General of WHO, or for which the Director-General of WHO has issued recommendations to prevent or detect communicable disease events. *Id*. at § 70.1(3)-(5).

HHS requested public comment on the definition of public health emergency. (Doc. 1-3, at 1-2.) In its final rule published on January 19, 2017, HHS explained that public health emergency used in Section 361(a) of the Public Health Services Act differs from how the term is used in other provision of the PHSA because it could be used to isolate and examine specific individuals (those in the precommunicable stage of a quarantinable communicable diseases) if the disease was likely to cause a public health emergency (82 Fed. Reg. 6905 Jan. 19, 2017). (Doc. 1-3, at 2-3.) HHS believed it necessary to define public health emergency because it "is a statutory prerequisite to the apprehension and examination of individuals in the precommunicable state of a quarantinable communicable disease." (Doc. 1-3 at 3.) In the 2017 Final Rule, HHS considered and rejected comments expressing concerns that references to WHO relinquished U.S. sovereignty, explaining that HHS and/or the CDC would continue to make its own decisions regarding when a quarantinable communicable disease may be likely to cause a public health emergency and when it would apprehend or detain individuals. (Doc. 1-3, at 3.)

B. HHS quarantines thousands of individuals from Wuhan, China in response to the risks associated with the COVID-19 pandemic.

In response to COVID-19, HHS later repatriated approximately 1,100 individuals who had been in Wuhan, China or who had been onboard the *Diamond Princess* cruise ship in Yokohama, Japan, and quarantined them in the United States for 14 days. (Doc. 1-3, at 3.) HHS later quarantined another 2,000 individuals who were onboard the *Grand Princess* cruise ship in San Francisco, California. (Doc. 1-3, at 4.) HHS relied on various regulations to detain these individuals, including 42 C.F.R. §§ 70.6, 71.23(a), and 71.33.

C. The States submit a petition of proposed rulemaking.

On July 18, 2022, more than five years after publication of the final rule, various States submitted a petition to amend that definition.[2] (Doc. 1-2.) However, HHS considered and rejected the petition. (Doc. 1-3.) HHS explained that the language and structure of the regulations (finalized in 2017) and agency practice in implementing its regulations were carried out subject to HHS/CDC's independent judgment. (Doc. 1-3 at 3.) HHS also rejected the States' concerns regarding purported political influence on the WHO's decision-making as a reason to remove the three definitions of public health emergency. (*Id*. at 4.) While the WHO developed International Health Regulations, those regulations had not been fully implemented by various nations. (*Id*.) Although the United States consulted with the WHO regarding international regulations, international

[2] Numerous States joined the petition for rulemaking (Doc. 1-3, at 1, n.1), but only Texas and Oklahoma filed this suit.

regulations do not provide the WHO with enforcement powers and do not authorize WHO to interfere in the United States' internal decision-making process. (*Id*. at 4–5.) Claims that the international regulations diminished U.S. sovereignty "are false." (*Id*. at 5.) HHS also addressed and rejected the States' allegation that HHS/CDC would not be harmed by deleting the three definitions because the definitions were important for the public and an expenditure of agency resources to amend the definitions was not justified. (*Id*. at 6.)

D. The States sue HHS under the APA.

This lawsuit has followed. In a four-count complaint, the States bring claims against Defendants under APA seeking declaratory and injunctive relief. (Doc. 1, at 2.) The States assert that HHS's definition of public health emergency authorizes HHS to act solely on decisions of the Director of the WHO or member states, improperly delegates decisions regarding public health emergencies to WHO or members of WHO, and "potentially permits the federal government to encroach" or infringe upon State sovereignty in violation of the Constitution.[3] (Doc. 1, ¶¶ 2, 17, 21, 67-75 (Count 4).) The States aver that HHS refused to adequately answer their petition for rulemaking

[3] The States oppose the definition of public health emergency as an "unlawful regulation." (Doc. 1, at ¶ 17.) According to the States, "the existing definitions [of public health emergency] exceed HHS's authority by unlawfully delegating their decisions to foreign nations or international organizations, absent express permission from Congress." (Doc. 1, at ¶ 24.) The States contend that WHO allows political factors to influence its health determinations and WHO was subject to politically-based manipulation in handling the COVID pandemic. (*Id*.) At various times, the States also claim that federal *statutes* and regulations "permit the federal government to encroach on State property and detain State Personnel in public health emergencies." (Doc. 1, at ¶ 20.) However, the States do not appear to challenge relevant statutes but only the regulatory definition of public health emergency. (Doc. 1 at 18.)

related to these definitions. (Doc. 1, ¶¶ 2, 35-46, (Counts 1).) They also contend that HHS's refusal to repeal the definition of public health emergency is arbitrary and capricious. (Doc. 1, at ¶¶ 47-66) (Counts 2-3).) They ask the Court to set aside the three alleged unlawful definitions. (Doc. 1, ¶ 75, Prayer for Relief, at 18.) Alternatively they ask the Court to grant the petition for rule-making, or alternatively, remand their petition for rulemaking for an adequate response to that petition. (Doc. 1, at 18.)

III. Legal Standards

The States' claims should be dismissed for lack of subject matter jurisdiction under Rule 12(b)(1). "Motions filed under Rule 12(b)(1) of the Federal Rules of Civil Procedure allow a party to challenge the subject matter jurisdiction of the district court to hear a case." *Ramming v. United States*, 281 F.3d 158, 161 (5th Cir. 2001). To survive a Rule 12(b)(1) motion, a plaintiff bears the burden to establish a court's jurisdiction. *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992). It is "presume[d] that federal courts lack jurisdiction unless the contrary appears affirmatively from the record." *DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 342 n.3 (2006) (citation omitted). "[I]n examining a Rule 12(b)(1) motion, a district court is empowered to find facts as necessary to determine whether it has jurisdiction." *Machete Prods., LLC v. Page*, 809 F.3d 281, 287 (5th Cir. 2015). Accordingly, "the district court may consider evidence outside the pleadings and resolve factual disputes." *In re Compl. of RLB Contracting, Inc.*, 773 F.3d 596, 601 (5th Cir. 2014); *see also Williamson v. Tucker*, 645 F.2d 404, 413 (5th Cir. 1981) (on a Rule 12(b)(1) motion, a district court is "free to weigh the evidence and satisfy itself . . . of its power to hear the case") (citation omitted.)

IV. Argument and Authorities

A. The States lack standing to challenge the definition of a public health emergency related to the quarantine of individuals.

Standing to sue is a doctrine rooted in the traditional understanding of a case or controversy. *Spokeo, Inc. v. Robins*, 578 U.S. 330, 338 (2016). The law of Article III standing "serves to prevent the judicial process from being used to usurp the powers of the political branches." *Id*. (quoting *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 408 (2013)).

To establish Article III standing to resolve a case or controversy, a plaintiff must show (i) that he suffered an injury in fact that is concrete, particularized, and actual or imminent; (ii) that the injury was likely caused by the defendant; and (iii) that the injury would likely be redressed by judicial relief. *TransUnion LLC v. Ramirez*, 141 S. Ct. 2190, 2203 (2021) (citing *Lujan*, 504 U.S. at 560–561). If the plaintiff does not claim to have suffered an injury that the defendant caused and the court can remedy, there is no case or controversy for the federal court to resolve. *TransUnion*, 141 S. Ct. at 2203 (citing *Casillas v. Madison Avenue Assocs., Inc*., 926 F.3d 329, 333 (7th Cir. 2019)). "Article III standing requires a concrete injury even in the context of a statutory violation," regardless of whether a statutory right is procedural or substantive. *Perez v. McCreary, Veselka, Bragg & Allen, P.C*., 45 F.4th 816, 823 (5th Cir. Aug. 15, 2022) (quoting *TransUnion*, 141 S. Ct at 2205). Legal infractions alone do not constitute concrete harm for the purpose of standing. *TransUnion*, 141 S. Ct. at 2205 ("[U]nder Article III, an injury in law is not an injury in fact."). "No concrete harm, no standing."

Id. at 2200.

Despite "special solicitude" given to States, they too must prove "an injury that is 'concrete, particularized, and actual or imminent; fairly traceable to the challenged action; and redressable by a favorable ruling.'"[4] *Texas v. United States* (*Texas INS Enforcement*), 40 F. 4th 205, 215–16 (5th Cir. 2022) (citations omitted); *see also Texas v. United States* (*Texas DACA*), 50 F. 4th 498, 513 (5th Cir. 2022).

The States challenge HHS's regulatory definition of public health emergency. They argue that three of the five definitions are unlawful because they improperly delegate the United States' or States' authority to foreign nations or international organizations. (Doc. 1, ¶¶ 35–59) (Counts 1, 2).) But the States have not alleged an injury that is "'concrete, particularized, and actual or imminent; fairly traceable to the challenged action; and redressable by a favorable ruling.'" *See Texas INS Enforcement*, 40 F. 4th at 215–16. Nor have the States identified an imminent or substantial risk of harm. *See TransUnion*, 141 S. Ct. at 2210. The States cannot show that the three definitions of a public health emergency that reference WHO are traceable to any harm or even a risk of harm to the States that would support standing.

[4] The Fifth Circuit has held that "special solicitude" has two requirements: (1) the State must have a procedural right to challenge the action, and (2) the challenged action must affect one of the State's quasi sovereign interests. *Texas DACA*, 50 F. 4th at 514. The Complaint identifies a "quasi-sovereign interest in the health and well-being of their residents against unlawfully intrusive action delegation," (¶ 22), but does not identify what that speculative action may be nor how it would impact the health and well-being of Plaintiffs' residents. In any event, "it is no part" of a State's "duty or power to enforce [its residents'] rights in respect of their relations with the Federal Government," *Alfred L. Snapp & Son, Inc. v. Puerto Rico ex rel. Barez*, 458 U.S. 592, 607, 610 n.16 (1982) (quoting *Massachusetts v. Mellon*, 262 U.S. 447, 485-86 (1923)).

1. The States have not shown a concrete injury that is traceable to HHS's definition of a public health emergency.

Plaintiffs cannot show that the challenged definition has been or will be used in a way that causes a concrete harm. Section 70.1, which includes five definitions, explains what the term "public health emergency" means. 42 C.F.R. § 70.1 Each of the five definitions is accompanied by an "or," meaning that each of the five definitional predicates may establish a "public health emergency." The States' umbrage is directed toward the last three definitions, which identify a public health emergency as a communicable disease event (3) which is notified to the World Health Organization as one that may constitute a public health emergency, (4) which is determined by the World Health Organization to constitute a public health emergency, or (5) which WHO has issued temporary or standing recommendations to prevent or detect the communicable disease. 42 C.F.R. § 70.1(3)-(5).

All of these definitions assist HHS in determining whether a public health emergency from a communicable disease actually exists. And, as HHS previously advised (Doc. 1-3, at 4), these regulatory definitions inform the public of what HHS *may* consider when determining whether a public health emergency exists. The three definitions recognize that the WHO may determine that a communicable disease event may occur or has occurred. But the existence of a public health emergency from a communicable disease, as defined in Section 70.1, does not authorize any action—even if it is a predicate to action. A communicable disease *may* be a threat or a concern to public health (anywhere)—and it *may* spread. For example, a communicable disease event

determined by WHO may be a threat or concern to a population or a subset of a population in another country or on another continent, but that disease event may not be a concern to the United States and may not spread to the United States. Each definition contained in the regulation is but one tool or measure to identify a communicable disease of which HHS may take note and if concerned, may take action. Plaintiffs incorrectly attempt to characterize these definitions as an automatic trigger to the exercise of HHS's and CDC's authority, such that a decision made by WHO about any number of public health situations in the world would somehow compel HHS or CDC to declare a public health emergency in the United States.

Moreover, the 2017 Final Rule makes clear that federal isolation and quarantine events are expected to be rare events, with the 2017 Final Rule estimating CDC might issue 1-2 quarantine or isolation orders in any given year, and that these orders would be issued to an individual and on a temporary basis. *See* 82 Fed. Reg. at 6916 ("CDC notes that historically, the issuance of Federal orders is rare (*i.e.*, one to two orders issued per year). The fact that the recent COVID-19 pandemic was an unprecedented public health situation requiring CDC to exercise its quarantine/isolation authority in no way foretells an increase in the frequency of such public health events or any change in the Government's approach to the use of this extraordinary authority. It also bears noting that the public health emergency declarations issued (and renewed multiple times) in response to the COVID-19 pandemic never relied on a determination by WHO as a justification; for instance, the first declaration noted confirmed cases in the United States, and the most recent renewal noted the continued consequences of the COVID-19

pandemic.[5]

Other statutes and regulations provide discretionary authority to HHS/CDC to take action. For example, 42 U.S.C. § 247d explains that "if the Secretary determines . . . that a disease or disorder present a public health emergency, . . . the Secretary *may* take such action as may be appropriate to respond to the public health emergency." (emphasis added). A different statute, 42 U.S.C. § 264(a), permits the Secretary "to make and enforce such regulations as *in his judgment* are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the Sates or possessions, or from one State or possession into any other State or Possession." (emphasis added). These statutes provide discretionary authority to the Secretary to respond to a "public health emergency."

Even if the States disagree with one or more definitions of public health emergency related to quarantine of individuals, the three definitions do not trigger any action that would or could pose a harm or even a risk of harm to the States. The definitions do not identify the scope or the exigency of a threat, the harm that may occur, or the steps that should be taken—let alone direct HHS or CDC to act. While the definitions may be a predicate to action by HHS/CDC, the definitions that identify a

[5] *See* Determination That a Public Health Emergency Exists (Jan. 31, 2020) ("*As a result of confirmed cases* of 2019 Novel Coronavirus (2019-nCov) . . . .) (emphasis added), *available at* https://aspr.hhs.gov/legal/PHE/Pages/2019-nCoV.aspx; *see also* Renewal of Determination That a Public Health Emergency Exists As a Result of the Continued Consequences of the Coronavirus Disease 2019 (COVID-19) Pandemic, (Feb. 9, 2023) ("*As a result of the continued consequences of the Coronavirus Disease 2019 (COVID-19) pandemic* and to allow for an organized and coordinated transition from this unprecedented public health emergency . . . .) (emphasis added), *available at* https://aspr.hhs.gov/legal/PHE/Pages/COVID19-9Feb2023.aspx.

public health emergency do not require any action. The States' abstract disagreement with part of a definition that may or may not be used in the future is not a concrete injury to a sovereign interest. Plaintiffs certainly cannot show that such speculative and unspecified future action is causing "certainly impending" harm to the States' interest.

The States cannot trace an injury from the definition of a public health emergency to their interest in the well-being of their populations where the definitions themselves do not authorize HHS to act and do not intrude upon the States' ability to act. In sum, no concrete, particularized, actual or imminent harm fairly traceable to the challenged action (three definitions of a public health emergency) has been shown to support standing. *See Texas INS Enforcement*, 40 F. 4th at 215–16.

2. There is no injunctive relief that would redress any injury.

The States also have not shown that they have suffered a concrete harm or face a certainly impending future concrete harm, and thus, injunctive relief will not redress any injury. Requests for injunctive and declaratory relief implicate the intersection of the redressability and injury-in-fact requirements. *Stringer v. Whitley*, 942 F.3d 715, 720 (5th Cir. 2019). Plaintiffs seeking injunctive and declaratory relief can satisfy the redressability requirement only by demonstrating a continuing injury or threatened future injury. *Id*. That continuing or threatened future injury, like all injuries supporting Article III standing, must be an injury in fact. *Id*. To be an injury in fact, a threatened future injury must be (1) potentially suffered by the plaintiff, not someone else, (2) "concrete and particularized," not abstract; and (3) "actual or imminent, not 'conjectural' or 'hypothetical.' *Id*. at 721. "[F]uture harm can satisfy the concrete-harm requirement

. . . so long as the risk of harm is sufficiently imminent and substantial." *TransUnion*, 141 S. Ct. at 2210.

The Supreme Court has repeatedly held that "[a]llegations of possible future injury are not sufficient;" rather, any threatened injury must be "certainly impending" to constitute injury in fact. *Clapper*, 568 U.S. at 409; *see also Lujan*, 504 U.S. at 564 n.2. The purpose of the requirement that the injury be "imminent" is "to ensure that the alleged injury is not too speculative for Article III purposes." *Clapper*, 568 U.S. at 409; *see also TransUnion*, 141 S. Ct. at 2212 (finding that the risk of dissemination of information to third parties was too speculative to support Article III standing).

Here, the States have not shown any past or future injury that is redressable by this Court. The definitions of a public health emergency do not compel HHS to take any action to prevent the spread of communicable diseases or impede the right of the States to identify and respond to a public health emergency. The definitions may inform HHS (and the public) of what constitutes a public health emergency either in this country or abroad, but the definitions themselves do not authorize any action by HHS or establish a concrete harm that is redressable here.

The States also have not shown any *concrete* harm because they appear to speculate that a sequence of events *may* occur as a result of the three definitions at issue: (a) that HHS may *disagree* with WHO that an event involving a communicable disease has occurred *but* (2) relying *solely* on the WHO's determination that a public health emergency exists (and not its own independent analysis that such emergency exists), HHS would take action to contain or address the communicable disease, *and* (3) HHS's

determination of what action to take would infringe on the State's right to take actions to protect its populations from HHS's response to that public health emergency. Texas does not allege any facts that suggest that this sequence of events actually occurred, is likely to occur, or is imminent.

The States also have not identified a substantial harm to the States from the definition of public health emergency, even if this sequence actually did or would occur. The States have not pointed to any action by HHS as a result of the definitions that actually infringed on their sovereignty or rights. The States aver that the definitions are unlawful—but this allegation is an injury in law, not an injury in fact. *See TransUnion*, 141 S. Ct at 2205. Layers of speculation do not establish any harm that would conceivably support standing or a request for injunctive relief. *See Louisiana ex rel. Landry v. Biden*, No. 22-30087, 2022 WL 866282, at *2 (5th Cir. Mar. 16, 2022) (finding government defendants were likely to succeed on the merits because the plaintiff States lacked standing where plaintiff States failed to meet their burden on causation and redressability). The States' claims should be dismissed for lack of standing.

B. Even if the States could establish standing, their claims fail as unripe.

"[A] ripeness inquiry is often required when a party is seeking pre-enforcement review of a law or regulation." *Roark & Hardee LP v. City of Austin*, 522 F.3d 533, 544 (5th Cir. 2008). "The ripeness doctrine's 'basic rationale is to prevent the courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements . . . .'" *Choice Inc. of Tex. v. Greenstein*, 691 F.3d 710, 715 (5th Cir. 2012); *Nat'l Park Hospitality Ass'n v. DOI*, 538 U.S. 803, 807 (2003). "A court should

dismiss a case for lack of 'ripeness' when the case is abstract or hypothetical," and "the key considerations are 'the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration.' *Choice Inc. of Tex*, 691 F.3d at 715. A claim is not ripe if it is "rests upon 'contingent future events that may not occur as anticipated, or indeed may not occur at all.'" *Texas v. United States*, 523 U.S. 296, 300 (1998) (citations omitted).

Here, the challenged portions of the definition do not create any legal rights or obligations, and Plaintiffs' claim rests on potential future interpretations and application of the public health emergency definitions, which could conceivably be one precondition for possible future interstate quarantine actions. The validity of such actions would depend on a host of factual circumstances not available to the Court at this time, including to what extent the agency relied on the challenged portions of the definitions and whether such reliance was accompanied by independent judgment, as well as whether the other prerequisites for quarantine orders were met. Thus, the issues are not fit for judicial review at this time, and would benefit from further factual development. Even if a purely legal issue were presented, however, Plaintiffs would still have to show some hardship in order to establish ripeness. *Choice Inc. of Tex*, 691 F.3d at 715. This they cannot do. The States are not conceivably suffering any hardship as a result of the existence of a definition with which they disagree. The Court should dismiss these claims as unripe.

C. Even if the States could establish standing, they cannot establish that the definition of public health emergency to isolate or quarantine individuals is arbitrary or capricious.

The APA "sets forth the procedures by which federal agencies are accountable to the public and their actions subject to review by the courts."[6] *Dep't of Homeland Sec. v. Regents of the Univ. of Cal.*, 140 S. Ct. 1891, 1905 (2020). The APA requires agencies to engage in "reasoned decisionmaking", and directs that agency actions be "set aside" if they are "arbitrary" or "capricious." *Id*. (citing *Michigan v. EPA*, 576 U.S. 743, 750 (2015); 5 U.S.C. § 706(2)(A)). Under this "narrow standard of review," a court is not to substitute its judgment for that of the agency, but instead to assess only whether the decision was "based on a consideration of the relevant factors and whether there has been a clear error of judgment." *Id*. (citing *FCC v. Fox Television Stations, Inc*., 556 U.S. 502, 513 (2009); *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971) (internal quotation marks omitted)); *Sierra Club v. U.S. Dep't of Interior*, 990 F.3d 909, 913 (5th Cir. 2021). Although the APA establishes a basic presumption of review for legal wrongs due to agency action, the presumption can be rebutted by a showing that the

[6] Generally speaking, judicial review of agency action proceeds on the basis of an administrative record, *Citizens to Pres. Overton Park, Inc. v. Volpe*, 401 U.S. 402 (1977), and if this matter proceeds to summary judgment, the agency will compile and certify the administrative record for the denial of the rulemaking petition. At the Motion to Dismiss stage, the Court may take judicial notice of key documents from the administrative record. *See, e.g., Hawkins v. AT&T*, No. 3:12-CV-1173-L, 2013 WL 4505154, at *3 (N.D. Tex. Aug. 23, 2013) ("Documents contained in a Title VII administrative record are public records for which the court can take judicial notice and consider in a motion to dismiss."); *Tanzy v. Mayorkas*, No. 3:20-CV-3161-X-BH, 2021 WL 3625076, at *3 (N.D. Tex. July 20, 2021) (considering agency documents attached to complaint), report and recommendation adopted, No. 3:20-CV-03161-X-BH, 2021 WL 3618109 (N.D. Tex. Aug. 16, 2021); *see also Marshall Cnty. Health Care Auth. v. Shalala*, 988 F.2d 1221, 1226 (D.C. Cir. 1993) (holding that the district court "can consult" the administrative record to answer the legal questions before the court even on a motion to dismiss).

relevant statute "preclude[s]" review, § 701(a)(1), or that the "agency action is committed to agency discretion by law," § 701(a)(2). *Dep't of Homeland Sec.*, 140 S. Ct. at 1905.

The scope of review under the "arbitrary and capricious" standard is narrow and highly deferential. *Sierra Club*, 990 F.3d at 913. A court is not to substitute its judgment for that of the agency. *Id*. Nevertheless, the agency must examine the relevant data and articulate a satisfactory explanation for its action including a "rational connection between the facts found and the choice made." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co*., 463 U.S. 29, 43 (1983). Normally, an agency rule would be arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider,[7] entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise. *Id*. The court may nevertheless uphold an agency's decision of "less than ideal clarity if the agency's path may reasonably be discerned." *Sierra Club*, 990 F.3d at 913 (citations omitted). An agency's denial of a petition for rulemaking may be reviewable agency action, but "as a substantive matter, such review is 'extremely limited' and 'highly deferential.'" *Gulf Restoration Network v. McCarthy*, 783 F.3d 227, 234 (5th Cir. 2015); *see also Cmty. Fin. Servs. Ass'n of Am. v. Consumer Fin. Prot. Bureau*, 51 F.4th 616, 630 n.4 (5th Cir. 2022).

[7] The States do not point to any authority that Congress does not intend for HHS to consider any data or decisions by international bodies who also assess whether a public health emergency from a communicable disease exists outside U.S. borders.

1. In response to the States' petition, HHS articulated a satisfactory explanation for its denial of the petition regarding the three definitions of a public health emergency.

HHS reasonably did not initiate new rulemaking, engaged in "reasoned decisionmaking" when including all five definitions of public health emergency, and explained its reasoning in denying the States' Petition for Rulemaking.[8] *See Michigan*, 576 U.S. at 750; *Gulf Restoration Network*, 783 F.3d at 234. The States served a Petition for Rulemaking, regarding HHS's definitions of public health emergency, challenging the inclusion of the three definitions as an "unlawful delegation" of its judgment. (Doc. 1-2 at 1–6.) Responding to that petition, HHS explained that the purpose of the new definitions was to provide the public with a clear understanding of HHS's authority for interstate quarantine, isolation, or conditional release as set forth in other regulations. (Doc. 1-3, at 2–3.) In addition, inclusion of references to WHO was not based on political considerations but was intended "to inform the public of the circumstances that HHS/CDC may consider when determining a public health emergency exists." (Doc. 1-3 at 4, 6.) Given the lessons learned during the COVID-19 pandemic, HHS believed it was important to reference WHO to increase transparency, improve rapid pathogen information sharing, and build strong response coordination. (Doc. 1-3 at 4.) In addition, the exercise of authority (which is not contained within the definitions) is found in other

[8] To the extent the Court finds the definitions of public health emergency constitute rule making, the Court may find that the agency's denial of a petition for rule making is presumptively reviewable. *Gulf Restoration Network*, 783 F.3d at 235. However, because the States have not established standing and the agency's decision to include all definitions are reasonable, the States' request to remand for a response to their petition for rule making should be denied and the claims dismissed.

regulations, including 42 C.F.R. Part 70 governing the isolation of individuals with quarantinable communicable diseases.[9] (Doc. 1-3, at 3.)

HHS specifically considered and expressly rejected the States' concern (reiterated here) that references to the WHO implicate U.S. sovereignty. (Doc. 1-3, at 3.) Thus, this is not a situation where a federal agency "entirely failed to consider an important aspect of the problem." *Cf. Motor Vehicle Mfrs. Ass'n of U.S., Inc*., 463 U.S. 29 at 43. HHS explained that it had and would continue to make its own independent decisions regarding when a quarantinable communicable disease may be likely to cause a public health emergency if transmitted to other individuals. (Doc. 1-3, at 3.) HHS also noted that agency practice since 2017 (during the COVID-19 pandemic) was consistent with HHS exercising its own independent judgment as to when and how to take action and quarantine individuals.[10] (*Id*. at 3–4.) As HHS explained, the "language and structure of the regulations, as well as the agency's practice" implementing those regulations, belies any contention that unlawful delegation occurred. (Doc. 1-3 at 4.) Instead, "apprehension and quarantine determinations are only carried out subject to the CDC Director's independent judgment." (*Id*.) HHS thus reasonably concluded that the

[9] For example, federal quarantine orders "must identify the individuals or groups to be quarantined, the location of the quarantine, explain the factual basis for the Director's reasonable belief that the individual is in the qualifying stage of the disease, explain the factual basis for the Director's reasonable belief that the individual is moving or about to move from one U.S. State into another or otherwise constitutes a probable source of infection to other individuals moving between U.S. States, explain that the order will be reassessed within 72 hours, and notify the individual of the opportunity for an agency medical review, as well as the potential for criminal penalties if non-compliant." (Doc. 1-3 at 3.)

[10] HHS provided two concrete examples with regard to quarantining passengers on two ships based on the Secretary's determination that COVID-19 constituted a public health emergency.

burdens of a new rulemaking were unwarranted under the circumstances.

HHS articulated clear reasons why it included the three definitions of a public health emergency in § 70.1. The States have not shown that the agency did not engage in reasoned decisionmaking—even if the States disagree with HHS's reasoning or ultimate conclusion—under the highly deferential standard for denial of a Petition for Rulemaking.

2. HHS reasonably included multiple definitions of a public health emergency.

And finally, it must be noted that the process by which HHS reached the definition is logical and rational. *See Michigan*, 576 U.S. at 750. The definitions merely explain what a public health emergency means. Having multiple definitions provides alternative measures for HHS to determine whether a public health emergency exists because of a communicable disease event. Considering multiple organizations' (or officials') views of a public health emergency gives HHS more data points, more facts, and more evidence to consider when deciding whether to take discretionary action. Including various definitions from other entities is particularly reasonable in this context because of the difficulty in identifying a public health emergency in the first place, especially where the communicable disease being considered does not originate in the United States, as with COVID-19. A determination that a public health emergency exists is based upon the nature of the threat, the source of the threat, the scope of the threat (how wide-spread, how it is communicated, how quickly it is communicated) and the effect of that condition on various populations (confined to one type of population, all populations, etc.). The

nature of the communicable disease itself may change both within and outside the United States, which may also inform HHS whether the potential for an emergency or existence of an emergency is waxing or waning. Multiple definitions (including the three definitions) are used by HHS as a guide to identify the threat—that may be exploding and impacting populations outside the United States even if it has not yet reached the United States. HHS promulgated multiple definitions of a public health emergency in manner that is transparent and takes into account the cross-border transmission of a communicable disease.

Even if HHS considers or relies upon the three definitions to determine that a health emergency exists, other statutes provide discretion for HHS to independently determine what action to take.[11] No decisions or actions are delegated beyond the federal government. The definitions only identify and explain what a public health emergency means. The three definitions, in particular, merely identify when an international organization believes a public health emergency exists as something HHS or the CDC may, but need not, consider. HHS's definitions of a public health emergency are logical and rational and do not violate the APA.

V. Conclusion

The States have not established standing to challenge HHS's definitions and their claims are not actually ripe. All of the States' claims against HHS should be dismissed

[11] The myriad assumptions on which the States conclusions rest do not establish that the agency's definitions of public health emergency violate the APA.

for lack of subject matter jurisdiction. Even if they have standing, HHS reasonably denied the State's Petition for Rulemaking with reasons, and HHS's definitions are not arbitrary or capricious. The States' complaint should be dismissed in its entirety.

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Respectfully submitted,

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Certificate of Service

On March 27, 2023, I electronically submitted the foregoing document with the clerk of court for the U.S. District Court, Northern District of Texas, using the electronic case filing system of the court. I hereby certify that I have served all parties electronically or by another manner authorized by Federal Rule of Civil Procedure 5(b)(2).

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