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

STATE OF TEXAS and STATE OF OKLAHOMA , Plaintiffs, v. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al., Defendants.	Civ. A. No. 4:23-cv-00066-Y

DEFENDANTS' REPLY TO
<u>PLAINTIFFS' RESPONSE TO DEFENDANTS' MOTION TO DISMISS</u>

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I. Introduction

The States' response is long on rhetoric but short of any substantive response to Defendants' motion to dismiss. The States have utterly failed to establish anything resembling a cognizable Article III injury. They baldly state that they have standing because another public health threat could emerge at any time, the World Health Organization (WHO) could declare a public health emergency in response to this threat, and—under the States' reading of the challenged regulations—HHS and CDC will somehow be compelled to blindly follow WHO's lead and exercise their public health powers in ways that will invade the States' sovereignty. Yet the States allege not a single extant fact in support of impending future harm that warrants this Court's intervention: for example, any pathogen that poses a future public health threat or any action that the States either will be forced to take or refrain from taking in response to this imagined future scenario as a result of Defendants' hypothetical future exercise of the challenged definitions. Their suit rests on pure, unbridled speculation.

Against this backdrop, the States urge the Court to ignore the requirements of Article III of the U.S. Constitution and essentially edit regulations they believe could have been better drafted on the basis that they are entitled to "special solicitude." But whatever special solicitude the States may have, it does not wholly excuse them from satisfying standing, a basic constitutional requirement to maintain their lawsuit.

Even if the States had standing and a ripe claim, they have not explained how the agency's definitions delegate any authority, or why the agency's decision not to initiate a rulemaking, review of which is extremely limited, was unreasonable.

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

The States have not pleaded and cannot show that the three challenged definitions of a public health emergency are traceable to any harm in the past or a risk of harm in the future to support standing. *See Texas v. United States* (*Texas INS Enforcement*), 40 F. 4th 205, 215–16 (5th Cir. 2022).

1. The States fail to establish a concrete injury as required to establish standing.

The States allege that they have standing because HHS detained thousands of individuals during COVID-19. (Resp. at 3, 9.) Their theory is that another public health threat could emerge at any time, WHO could declare a public health emergency in response to this threat, and HHS and CDC will be compelled to follow WHO's lead and exercise their public health powers in ways that will invade the States' sovereignty. (Resp. at 1, 7-13.) But as explained in Defendants' motion to dismiss, definitions do not authorize any action; they only inform the public of what HHS may consider when determining whether to take action to prevent the spread of a communicable disease. (Doc. 15 at 10–11.)

Yet in response to Defendants' motion, the States re-urge that the three definitions of public health emergency (which refer to WHO) operate as "an automatic trigger" to authorize federal mandatory quarantine orders, and "each quarantine order … will invade the quasi-sovereign interests of the States." (Resp. at 11, 21–22.) The States contend that the definitions "grant WHO substantial power over the lives of Texans and

Oklahomans" and "unlawfully delegate[] power to WHO.'" [1] (Resp. at 14–15.) According to the States, "the regulation is on the books and operative; it could be invoked at any time, without any more legislative or regulatory action." (Resp. at 15.)

This hyperbole—that imbues definitions with power—is inaccurate and misleading.[2] Definitions do not possess self-executing power "without any more legislative or regulatory action." Definitions, by their nature, do not grant authority or trigger action. The government's discretionary authority to prevent the transmission of disease is provided by multiple statutes and regulations.[3] While a finding that a disease is likely to cause a "public health emergency" is one of several findings necessary to take certain specific discretionary actions, the existence of WHO's determination of a public health emergency does not trigger or mandate any action by HHS or CDC. The federal

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[1] The States may disagree with the federal government's consideration of information compiled, analyzed, and published outside the United States, including scientific and international data, articles and opinions. But the States' opinions regarding information considered and relied upon by federal authorities when deciding a course of action are not relevant to the salient issue: whether a *definition* of public health emergency unlawfully delegates power to international organizations to take action within the United States and infringes on States' rights or delegates United States authority to foreign nations or international organizations. (Doc. 1, ¶ 2, 24; *see id*., ¶¶ 35–59) (Counts 1, 2).)

[2] The States repeatedly conflate the words "definitions" and "regulations." Definitions do not "regulate" in the sense that they operate as a triggering mechanism for action. Therefore, the States' imprecise references to "regulations" rather than "definitions" are misleading.

[3] HHS is authorized "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." 42 U.S.C. § 264(a). Under section 264(d), this authority extends to the quarantine and isolation of individuals moving between U.S. states or territories who are reasonably believed to be infected with a quarantinable communicable disease if appropriate standards are met. *Id*. at 264(d). [Defendants' motion inadvertently indicated that this authority is limited to the existence of a public health emergency. (Doc. 15, at 3.) More accurately, individuals in a precommunicable stage of a disease may be quarantined if the agency finds that the disease is likely to cause a public health emergency. No similar requirement attaches to the quarantine of individuals arriving into the United States from a foreign country.]

government may consider any of the five definitions of public health emergency (identifying a communicable disease event—here or abroad) along with other information to decide what action to take, if any. (Doc. 15, at 10–11.) Moreover, there are multiple procedural and substantive prerequisites to issuing interstate quarantine orders. *See generally*, 42 CFR Pt. 70.

The States' purported harm (that a definition invades State sovereignty) is rife with speculation. The States do not point to any fact that shows Defendants relied on the challenged definitions in the past (because Defendants have not), and there is no particular reason to think Defendants are likely to do so in the future. That is why, fundamentally, the States cannot show any cognizable injury (past or future) from any definition but merely allege unsupported and illogical layers of speculation—that the CDC will take action based *solely* on a WHO definition of public health emergency and without considering any other non-WHO information, despite vast resources of information within the United States and internationally. (Doc. 15, at 12–13.)

2. The States fail to establish imminent harm as required to establish standing.

The States have not actually identified an imminent or substantial risk of harm. *See TransUnion LLC v. Ramirez*, 141 S. Ct. 2190, 2210 (2021). 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 v. Amnesty Int'l USA*, 568 U.S. 398, 409 (2013); *see also Lujan v. Defs. of Wildlife*, 504 U.S. 555, 564 n.2 (1992). 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.

The States argue that "alleged health experts" state that "a future pandemic is 'almost guaranteed.'" (Resp. at 9.) But the existence of a pandemic does not trace any harm to the States. To establish an imminent threat of harm, the States must establish an imminent likelihood that WHO will determine a public health emergency exists (somewhere in the world) and HHS will then detain individuals in the United States, relying *only* on WHO's definition of public health emergency in finding that the disease is likely to cause a public health emergency. And they would also have to show an imminent risk of harm to their alleged sovereign interests.

There is no imminent threat of harm to State sovereignty to establish standing. The States argue that a series of events—that has never happened before—is imminent. But there are no facts that show HHS detained individuals based solely on a WHO definition of a public health emergency in the past or will take such action in the future. The States' abstract disagreement with three definitions that identify a public health emergency–a definition that may or may not be used in the future, and a definition that may or may not be the *only* information relied on by HHS when deciding to detain individuals—is not a concrete injury to a sovereign interest. The States certainly cannot show that such speculative and unspecified future action is causing "certainly impending" harm to the States' interest. (Doc. 15, at 11–15.)

B. Even if the States could establish standing, their claims are not ripe.

The States allege that their claim is ripe because the definitions "delegate power

unlawfully to an international body *now*," and this electorally-unaccountable international organization "could authorize quarantines entirely absent a pandemic." (Resp. at 15.) (emphasis original.) The States' argument is patently false. Nothing in the definitions allow WHO (or any other international organization) to authorize the detention of individuals in this country. The States have not alleged facts and cannot establish that the definitions of public health emergency delegate power to an international body or allow such body to detain individuals in the United States—past, present or future. And even if an international body could detain individuals in the United States (which it very obviously cannot), the States' claim would become ripe when that event actually occurred.[4] And on May 5, 2023, WHO announced that COVID-19 is no longer a global health emergency,[5] and HHS's COVID-19 public health emergency declaration expired on May 11, 2023.[6] There is no currently-existing public health threat that imminently threatens the States' sovereignty. The States' lawsuit is simply litigation in search of an injury. This is something the Constitution does not permit.

Moreover, the issues are not fit for judicial review and no arguable hardship is

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[4] States with standing *might* have ripe claims if WHO actually declared a public health emergency and the CDC actually began issuing quarantine orders *only* because WHO declared a public health emergency *and* without making any independent analysis or justification for its quarantine decision *and* that decision affected individuals in Texas or Oklahoma. But that series of events has not happened in the past, and there are no facts to infer that it may happen in the future. If all of these events transpired in the future (which is exceedingly unlikely), there is no reason to believe the States could not seek judicial review of agency actions based on a series of events that actually occurred at that time.

[5] *See* https://www.who.int/news/item/05-05-2023-statement-on-the-fifteenth-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-coronavirus-disease-(covid-19)-pandemic, last visited May 10, 2023.

[6] *See* https://oig.hhs.gov/coronavirus/covid-flex-expiration.asp, last visited May 10, 2023.

imposed absent a specific agency action taken pursuant to these challenged definitions. How the agency determines that a particular disease is "likely to cause a public emergency"—possibly justifying a particular quarantine order or set of orders—is a fact-dependent inquiry, and judicial review of the agency's reasoned decisionmaking would hinge on the contents of an administrative record supporting that decision. The Court should not preemptively review hypothetical questions of when the agency could rely on these definitions and what level of consideration of the WHO findings would be objectionable, particularly when there is no current or imminent threat of such action.

C. The denial of a rulemaking petition was reasonable because WHO definitions of public health emergency do not implicate the non-delegation doctrine and/or are not unlawful.

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). "A federal agency may not 'abdicate its statutory duties' by delegating them to a private entity." *State v. Rettig*, 987 F.3d 518, 531 (5th Cir. 2021), *cert. denied sub nom. Texas v. Comm'r of Internal Revenue*, 142 S. Ct. 1308 (2022) (citing *Sierra Club v. Lynn*, 502 F.2d 43, 59 (5th Cir. 1974)). But there are three specific types of legitimate outside party input into agency decision-making processes: (1) establishing a reasonable condition for granting federal approval; (2) fact gathering; and (3) advice giving. *U.S. Telecom Ass'n v. F.C.C.*, 359 F.3d 554, 566 (D.C. Cir. 2004). "[A]n agency does not improperly subdelegate its authority when it 'reasonabl[y] condition[s]' federal approval on an outside party's determination of some issue; such conditions only amount to legitimate requests for

input." *See Rettig*, 987 F.3d at 531 (citing *U.S. Telecom Ass'n*, 359 F.3d at 566–67).

The States argue that the challenged definitions "delegate emergency declaration authority to an[] international organization." (Resp. at 1.) Again, however, the States' theory—that the challenged definitions "delegate . . . authority"—is false. Thus, as further explained below, the non-delegation doctrine either does not apply at all (because the definitions do not delegate any authority) or the WHO definitions are not unlawful (because the definitions are for fact-gathering and/or giving advice to HHS). Either way, the definitions themselves are not unlawful.

1. The non-delegation doctrine does not apply because the WHO definitions of public health emergency do not delegate any authority.

HHS did not delegate any authority to an outside organization by promulgating multiple definitions of a public health emergency. The challenged definitions only identify a condition that may exist, according to Defendants or WHO. The WHO definitions may give HHS more input into analyzing the conditions that may constitute a public health threat to individuals in the United States. But the definitions do not divest HHS of its authority to take action because HHS's authority to take action to detain individuals is found elsewhere in the regulations. HHS has discretionary authority to take action even if WHO actually identifies a public health emergency somewhere in the world. Thus, the non-delegation doctrine does not apply.

2. Even if the non-delegation doctrine applies, the WHO definitions of public health emergency are not unlawful.

The non-delegation doctrine itself provides exceptions where an agency may legitimately rely on or consider outside party input into its decision-making processes for

fact gathering and advice. *See U.S. Telecom Ass'n*, 359 F.3d at 566. A predicate to federal decisionmaking is reasonable if there is "a reasonable connection between the outside entity's decision and the federal agency's determination." *See Rettig*, 987 F.3d at 531. For example, in *Rettig*, the Fifth Circuit held that HHS did not unlawfully delegate authority to an outside board.[7] *Id*. at 527, 532. Even though HHS "incorporated the Boards' actuarial standards into its Certification Rule," the Fifth Circuit found the Certification Rule was a reasonable condition, and HHS's sub delegation of certain actuarial soundness requirements to the Board did not divest HHS of its final reviewing authority. *Id*. at 533.

Similarly in this case, the definitions of public health emergency do not divest HHS of its authority. Multiple definitions of the existence of a public health emergency that an agency may consider are imminently reasonable, given that health conditions, biological in nature, are amorphous. 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. (Doc. 15, at 21.) At most, the WHO definitions provide additional information, additional facts, and/or advice that a public health emergency may exist somewhere, including in the United States. This type of fact-gathering and/or advice in deciding what action to take is not an unlawful delegation of authority. *See U.S. Telecom Ass'n*, 359 F.3d at 566.

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[7] In *Rettig*, the States alleged a concrete injury from a loss of millions of dollars related to HHS's Certification Rule. *Rettig*, 987 F.3d at 528. As previously explained, however, the States have not alleged a concrete injury in this case.

3. The agency reasonably declined to initiate a rulemaking under these circumstances.

Defendants disagree with the States' interpretation of the definitions and their relevance for the above given reasons. But regardless of the States' inaccurate view of the import of the challenged definitions, the agency's denial of the States' petition for rulemaking would be reasonable in light of the fact the agency has never used these definitions as the States claim they could. "Agency practice since 2017 accords with the understanding that CDC would only consider WHO's determinations when exercising its own independent judgment regarding apprehension and detention of individuals." (Doc. 1-2, at 3.) Given that CDC has not exercised the authority in the way the States fear and has disavowed any intention of doing so, there is no arguable need to waste finite agency resources on purely hypothetical issues. *Id*. at 6.

II. Conclusion

The States have not established standing to challenge HHS's definitions because they cannot show a concrete harm or an imminent risk of harm. In addition, their claims are not ripe. Even if the States could establish standing and ripeness, the definitions do not unlawfully delegate any authority to WHO and the agency reasonably included multiple definitions of the existence of a public health emergency. The States' complaint should be dismissed in its entirety.

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Respectfully submitted,

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Certificate of Service

On May 15 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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