### 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

### **RESPONSE IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS**

## TABLE OF CONTENTS

In	TRO	DDUCTION
BA	CK	<u>GROUND</u>
AR	GU	<u>ment</u>
I.	ſ	<b>Texas and Oklahoma have standing to bring this lawsuit.</b>
	A.	Texas and Oklahoma are entitled to special solicitude when it comes to standing
	В.	Texas and Oklahoma have sufficiently pleaded injury-in-fact
	С.	Texas and Oklahoma have met the other standing requirements
	D.	Texas and Oklahoma's case is ripe14
II.	ſ	The Defendants' denial of the rulemaking petition was arbitrary and capricious15
	A.	The Defendants' denial of the petition for rulemaking was arbitrary and capricious
	В.	The challenged definitions violate the delegation doctrine
		1. The definitions are unlawful delegations because the Defendants lack specific authorization from Congress
		2. The definitions are unlawful because the Defendants exercise no 'meaningful oversight' over the WHO
		3. The Defendants mischaracterize the three definitions as discretionary

## **TABLE OF AUTHORITIES**

## Cases

Abbott Labs. v. Gardner, 387 U.S. 136 (1967)	14
<i>Alexander v. Sandoval</i> , 532 U.S. 275 (2001)	
Alfred L. Snapp & Son, Inc. v. P.R., ex rel., Barez, 458 U.S. 592 (1982)	7
Anderson v. Sch. Bd. of Madison Cty., 517 F.3d 292 (5th Cir. 2008)	14
Ashcroft v. Iqbal, 556 U.S. 662 (2009)	6
Babbitt v. United Farm Workers Nat. Union, 442 U.S. 289 (1979)	9
Bell Atl. Corp. v. Twombly, 550 U.S. 544 (2007)	5
Bond v. United States, 572 U.S. 844 (2014)	
Calhoun v. Hargrove, 312 F.3d 730 (5th Cir. 2002)	6
Children's Health Def. v. Facebook Inc., 546 F. Supp. 3d 909 (N.D. Cal. 2021)	
Compassion Over Killing v. U.S. FDA, 849 F.3d 849 (9th Cir. 2017)	
Contender Farms, L.L.P. v. U.S. Dep't of Agric., 779 F.3d 258 (5th Cir. 2015)	
Cornerstone Christian Schs. v. Univ. Interscholastic League, 563 F.3d 127 (5th Cir. 2009)	
Culbertson v. Lykos, 790 F.3d 608 (5th Cir. 2015)	6
DaimlerChrysler Corp. v. Cuno, 547 U.S. 332 (2006)	
Davis v. Federal Election Comm'n, 554 U.S. 724 (2008)	
<i>Field v. Clark</i> , 143 U.S. 649 (1892)	

## Case 4:23-cv-00066-Y Document 22 Filed 05/01/23 Page 4 of 32 PageID 334

<i>Gulf Restoration Network v. McCarthy</i> , 783 F.3d 227 (5th Cir. 2015)	
Johnson v. Johnson, 385 F.3d 503 (5th Cir. 2004)	6
<i>Kentucky v. Biden</i> , 23 F.4th 585 (6th Cir. 2022)	
La. Pub. Serv. Comm'n v. F.C.C., 476 U.S. 355 (1986)	
<i>Louisiana v. Becerra</i> , 577 F.Supp.3d 483 (W.D. La 2022)	
Loving v. United States, 517 U.S. 748 (1996)	
Lujan v. Defenders of Wildlife, 504 U.S. 555 (1992)	6, 7, 8, 9, 13, 16
Massachusetts v. EPA, 549 U.S. 497 (2007)	6, 7, 13, 16
<i>Michigan v. EPA</i> , 576 U.S. 743 (2015)	16
Mistretta v. United States, 488 U.S. 361 (1989)	
Motor Vehicle Mfrs. Ass'n of U.S. v. State Farm Mut. Auto. Ins., 463 U.S. 29 (1983)	
NAACP v. Fed. Power Comm'n, 520 F.2d 432 (D.C. Cir. 1975)	
Nat'l Ass'n of Home Builders v. Defenders of Wildlife, 551 U.S. 644 (2007)	
Nat'l Horsemen's Benevolent & Protective Ass'n v. Black, 53 F.4th 869 (5th Cir. 2022)	
Nat'l Park Hosp. Ass'n v. Dep't of Interior, 538 U.S. 803 (2003)	
New York v. U.S. Nuclear Regul. Comm'n, 589 F.3d 551 (2d Cir. 2009)	
Roark & Hardee LP v. City of Austin, 522 F.3d 533 (5th Cir. 2008)	
Sidag Aktiengesellschaft v. Smoked Foods Prod. Co., 960 F.2d 564 (5th Cir. 1992)	
<i>Spokeo, Inc. v. Robins,</i> 578 U.S. 330 (2016)	

## Case 4:23-cv-00066-Y Document 22 Filed 05/01/23 Page 5 of 32 PageID 335

13
14
9
15
14
13
9
13
6
6
24
20
22
21
21

## Statutes

5 U.S.C. § 553(e)	7
5 U.S.C. § 706	7
42 U.S.C. § 264(a)	
42 U.S.C. § 264(b)	

## Case 4:23-cv-00066-Y Document 22 Filed 05/01/23 Page 6 of 32 PageID 336

42 U.S.C. § 264(d)	
21 O.S. § 48-1195	
63 O.S. § 1-504	
Tex. Health & Safety Code § 81.001 et seq	
Tex. Health & Safety Code § 121.024	
Tex. Health & Safety Code § 122.005-006	

## **Other Authorities**

Coronavirus disease 2019 (COVID-19) Situation Report – 43, WHO, (Mar. 3, 2020)	5
Joyce Hackel, <i>A future pandemic is 'almost guaranteed,' Fauci says</i> , THE WORLD (May 21, 2021)	9
Salvatore Babones, Yes, Blame WHO for Its Disastrous Coronavirus Response, FOREIGN POLICY (May 27, 2020)	5
Tom Frieden, <i>Will We Be Ready for the Next Pandemic?</i> THE WALL STREET JOURNAL (Feb. 12, 2021)	9
Wendy E. Parmet & Michael S. Sinha, <i>Covid-19—The Law and Limits of Quarantine</i> , NEW ENGLAND J. MED. (Apr. 9, 2020)	2
WHO, Int'l Health Regulations 12, Art. 6 (3d Ed. 2005)	22
WHO, Int'l Health Regulations 14, Art. 12 (3d Ed. 2005)	23
WHO, Int'l Health Regulations 14, Art. 15 & 16 (3d Ed. 2005)	23
Yu-Jie Chen & Jerome A. Cohen, <i>Why Does the WHO Exclude Taiwan?</i> , COUNCIL ON FOREIGN RELATIONS (Apr. 9, 2020)	5

## Rules

42 C.F.R. § 70.1	10,	, 11,	14,	18, 2		23
------------------	-----	-------	-----	-------	--	----

## Regulations

82 Fed. Reg. 6890 (Jan.	19, 2017)	
82 Fed. Reg. 6905 (Jan.	19, 2017)	
82 Fed. Reg. 6916 (Jan.	19, 2017)	9

## **Constitutional Provisions**

U.S. Const., Art. I, § 1
--------------------------

#### **INTRODUCTION**

Our national experience with COVID-19 vividly emphasized the importance of sovereignty, accountability, and independent decision-making by government actors. Although numerous persons worked tirelessly to fight the virus, the pandemic exposed flaws in many institutions, perhaps none more so than the World Health Organization (WHO). WHO was both unprepared for COVID and compromised in its ability to deal with COVID by its close relationship with the totalitarian Chinese government. Among other things, its director was selected following aggressive behind-the-scenes politicking by China, it understated the transmissibility of COVID, it repeatedly parroted Chinese propaganda, and it once labeled "stigma" as more dangerous than the virus.

Despite this, the Defendants want to maintain unlawful regulations adopted on President Obama's last day in office that allow WHO to unilaterally establish the existence of a public health emergency in the United States. Because this delegation of power is unlawful and infringes on state sovereignty, and considering WHO's ignominious handling of COVID, a number of states in 2022 petitioned the Defendants with a simple and reasonable request: repeal this improper delegation so that emergency declaration authority is vested only in politically accountable actors in the United States. The Defendants denied the petition. Now that Texas and Oklahoma have sued to challenge the denial, the Defendants have moved to dismiss.

The motion should be denied. The Plaintiffs have standing to oppose this intrusion on their sovereignty, this case is ripe, and the Defendants' denial of the petition was arbitrary and capricious. Moreover, it is unlawful to delegate emergency declaration authority to any international organization, especially one as compromised as WHO. And the Defendants' insistence that the regulations do not mean what they say and that repealing them would be too burdensome is hokum.

#### BACKGROUND

The Defendants are 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). This exercise of federal power preempts conflicting State action. *Id.* § 264(e). The Defendants also possess the power to impose quarantines on persons in the United States. *Id.* § 264(d). They may detain persons "reasonably believed to be infected with a communicable disease in a qualifying stage" who will be moving between states or are a "probable source of infection" to people who will likely be traveling between states. *Id.* § 264(d)(1). The "qualifying stage" of a disease is "a communicable stage" or the "precommunicable stage, if the disease would be likely to cause a public health emergency" is therefore key to the scope and exercise of the Defendants' immense quarantine power.

On January 19, 2017—the last day of the Obama Administration—the Defendants published a final rule that defines "public health emergency" for the purpose of quarantine orders. 82 Fed. Reg. 6905 (Jan. 19, 2017). The Defendants acknowledged the significance of defining "public health emergency," affirming that a definition was "essential" because "the existence of such an emergency is a statutory prerequisite to the apprehension and examination of individuals in the precommunicable stage of a quarantinable communicable disease." Doc. 1-3 at 3.

The final rule defined "public health emergency" in five ways. The first two, which are not at issue, rely solely on determinations made by United States officials. The final three definitions, on the

<sup>&</sup>lt;sup>1</sup> The precommunicable stage "begins at a person's earliest opportunity for exposure to an infection and ends on the latest date at which the person could reasonably be expected to become contagious." Wendy E. Parmet & Michael S. Sinha, *Covid-19—The Law and Limits of Quarantine*, NEW ENGLAND J. MED. (Apr. 9, 2020), https://www.nejm.org/doi/full/10.1056/nejmp2004211.

#### Case 4:23-cv-00066-Y Document 22 Filed 05/01/23 Page 10 of 32 PageID 340

other hand, rely solely on information from, and determinations by, WHO. According to those definitions, a "public health emergency" is:

(3) Any communicable disease event the occurrence of which is notified to the World Health Organization, in accordance with Articles 6 and 7 of the International Health Regulations [IHR], as one that may constitute a Public Health Emergency of International Concern; or

(4) Any communicable disease event the occurrence of which is determined by the Director-General of the World Health Organization, in accordance with Article 12 of the [IHR], to constitute a Public Health Emergency of International Concern; or

(5) Any communicable disease event for which the Director-General of the World Health Organization, in accordance with Articles 15 or 16 of the [IHR], has issued temporary or standing recommendations for purposes of preventing or promptly detecting the occurrence or reoccurrence of the communicable disease.

42 C.F.R. § 70.1. Not only does each of these definitions depend solely on WHO and its member states, because the word "or" connects each of the definitions, any definition of the five will constitute a public health emergency.

During the COVID-19 pandemic, the Defendants exercised their emergency powers to quarantine thousands of people. Doc. 1-3 at 3-4. In particular, the Defendants acknowledge quarantining and "repatriat[ing] approximately 1,100 individuals from Wuhan, China" and "quarantin[ing] approximately 2,000 individuals from the *Grand Princess* cruise ship." *Id.* The Defendants relied solely on 42 C.F.R. § 70.6 to quarantine the *Grand Princess* passengers. *Id.* at 4. The Defendants admit that "[b]oth quarantine orders noted that the WHO Director General, pursuant to the IHR, had declared that the outbreak of COVID-19 constituted a Public Health Emergency of International Concern." *Id.* 

Two-and-a-half years after the beginning of the COVID-19 pandemic—and after observing multiple instances of WHO malfeasance—Oklahoma led a number of States in submitting a petition for rulemaking requesting the simple deletion of definitions (3), (4), and (5) of public health emergency in 42 C.F.R. § 70.1. Doc. 1-2. The States asserted that the definitions infringed on the police powers

#### Case 4:23-cv-00066-Y Document 22 Filed 05/01/23 Page 11 of 32 PageID 341

of the States and implicated their quasi-sovereign interests in the health and economic well-being of their populace. Broken down further, the petition made three basic contentions: (1) the definitions were an unlawful delegation to an international body, (2) changed circumstances justify the rulemaking because WHO's treatment of the COVID pandemic illustrated that it is an unreliable actor, and (3) the Defendants have denied that the United States needs to use the definitions as written. *Id.* 

The Defendants denied the petition. In doing so, they ignored the primary focus of the petition—namely, that the plain meaning of the definitions indicates that declarations made solely by WHO can determine that a public health emergency exists in the United States. *See* Doc. 1-3. Instead, the Defendants claimed that HHS "will continue to make its own independent decisions" when determining quarantine calls. *Id.* at 3. The Defendants also asserted that it is "important to include references to WHO in the definition of 'public health emergency' to inform the public of the circumstances that HHS/CDC *may* consider." *Id.* at 4 (emphasis added). The Defendants scoffed at the petition's third argument, stating that even if there were no harm to the Defendants from repealing the regulations, doing so was not worth "the expenditure of agency resources." *Id.* at 6.

The Defendants offered no defense of WHO's actions during the COVID pandemic. They "acknowledge[d] the concerns noted in the petition regarding purported political influence on WHO decision-making," but stated that these concerns "do not support removing references to that organization in" the regulations. *Id.* at 4. Why not? Because "[they] are committed to *strengthening* WHO so that it can be more effective, transparent, and agile, including the organization's ability to prepare for and respond to COVID-19 and the next pandemic." *Id.* (emphasis added). That is to say, the Defendants did not repeal the definitions because they want WHO to have *more* power.

It is understandable why the Defendants did not mount an actual defense of WHO, as such a defense would have been difficult. Throughout the early stages of the COVID pandemic, WHO was

#### Case 4:23-cv-00066-Y Document 22 Filed 05/01/23 Page 12 of 32 PageID 342

routinely asleep at the wheel, at *best*. But most importantly, China's malign influence on WHO weakened the global response to the pandemic—likely worsening the scope of the virus.

WHO entirely ignored a December 31, 2019, notice from the government of Taiwan that COVID might spread from human to human. Yu-Jie Chen & Jerome A. Cohen, *Why Does the WHO Exclude Taiwan?*, COUNCIL ON FOREIGN RELATIONS (Apr. 9, 2020).<sup>2</sup> Instead, WHO relied on the Chinese government to declare that there was "no clear evidence of human to human transmission" on January 12, 2020.<sup>3</sup> Later, of course, the world would find out that "a Chinese doctor had already concluded that the new disease was 'probably infectious' as early as Dec. 27." *Id.* 

Even after WHO belatedly declared COVID a public health emergency, it recommended against "any travel or trade restriction" because such actions could "promote stigma or discrimination." *Id.* WHO's Director-General was so concerned with the reputation of the Chinese government that he stated on March 2, 2020—in what bore no marks of being intended as hyperbole—that "stigma, to be honest, is more dangerous than the virus itself."<sup>4</sup> The very next day, WHO confirmed around three thousand recorded deaths from COVID.<sup>5</sup> WHO itself attributes almost 7 million more deaths worldwide to COVID since then.<sup>6</sup> WHO's uncritical acceptance of the data fed to it by the Chinese government delayed the international response to the pandemic.

#### ARGUMENT

To survive a motion to dismiss under Rule 12, the plaintiff needs only to plead "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007).

<sup>&</sup>lt;sup>2</sup> Available at https://www.cfr.org/in-brief/why-does-who-exclude-taiwan

<sup>&</sup>lt;sup>3</sup> Salvatore Babones, Yes, Blame WHO for Its Disastrous Coronavirus Response, FOREIGN POLICY (May 27, 2020), https://tinyurl.com/uhxrjb7z.

<sup>&</sup>lt;sup>4</sup> https://twitter.com/WHO/status/1234597035275362309

<sup>&</sup>lt;sup>5</sup> Coronavirus disease 2019 (COVID-19) Situation Report – 43, WHO, (Mar. 3, 2020), https://tinyurl.com/4xptcysh

<sup>&</sup>lt;sup>6</sup> Coronavirus (COVID-19) Dashboard, WHO, https://covid19.who.int/, accessed on Apr. 28, 2023.

#### Case 4:23-cv-00066-Y Document 22 Filed 05/01/23 Page 13 of 32 PageID 343

A claim is plausible when the factual allegations, accepted as true, "allow[] the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009); *Calhoun v. Hargrove*, 312 F.3d 730, 733 (5th Cir. 2002) (well-pleaded facts must be accepted as true and viewed in the light most favorable to a plaintiff). "The plausibility standard is not akin to a probability requirement, but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Culbertson v. Lykos*, 790 F.3d 608, 616 (5th Cir. 2015) (quotations omitted). A motion to dismiss cannot be granted "unless the plaintiff would not be entitled to relief under any set of facts ... consistent with the complaint." *Johnson v. Johnson*, 385 F.3d 503, 529 (5th Cir. 2004).

#### I. Texas and Oklahoma have standing to bring this lawsuit.

Texas and Oklahoma have "allege[d] facts that give rise to a plausible claim of [] standing," so dismissal under Rule 12(b)(1) is improper. *Cornerstone Christian Schs. v. Univ. Interscholastic League*, 563 F.3d 127, 134 (5th Cir. 2009). The States have pleaded facts demonstrating each element of standing: "(i) ... 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 v. Defenders of Wildlife*, 504 U.S. 555, 560–61 (1992)); *see also Spokeo, Inc. v. Robins*, 578 U.S. 330, 338 (2016).

#### A. Texas and Oklahoma are entitled to special solicitude when it comes to standing.

Courts have long "recognized that States are not normal litigants for the purposes of invoking federal jurisdiction." *Massachusetts v. EPA*, 549 U.S. 497, 518 (2007). States are "entitled to special solicitude in [the] standing analysis" because they "surrender[ed] certain sovereign prerogatives" when they entered the Union—including the exercise of certain police powers. *Id.* at 519, 520. Special solicitude relaxes the standing requirements. *See Texas v. United States*, 809 F.3d 134, 162 (5th Cir. 2015), *as revised* (Nov. 25, 2015). States are entitled to special solicitude when they make the two showings the States have made here: "(1) the State must have a procedural right to challenge the action in

#### Case 4:23-cv-00066-Y Document 22 Filed 05/01/23 Page 14 of 32 PageID 344

question, and (2) the challenged action must affect one of the State's quasi-sovereign interests." *Texas v. United States*, 50 F.4th 498, 514 (5th Cir. 2022) ("*Texas DACA*"). A party that "has been accorded a procedural right to protect his concrete interests can assert that right without meeting all the normal standards for redressability and immediacy." *Lujan*, 504 U.S. at 572 n.7.

As in many special solicitude cases, the States have a procedural right under the APA to challenge the Defendants' denial of the petition for rulemaking. See 5 U.S.C. §§ 553(e), 706. The Defendants' actions also implicate the States' quasi-sovereign interests. These "interests stand apart .... They are not sovereign interests, proprietary interests, or private interests pursued by the State as a nominal party. They consist of a set of interests that the State has in the well-being of its populace." *Alfred L. Snapp & Son, Inc. v. P.R., ex rel., Barez,* 458 U.S. 592, 602 (1982). "One helpful indication' of a quasi-sovereign interest is 'whether the injury is one that the State, if it could, would likely attempt to address through its sovereign lawmaking powers." *Texas DACA*, 50 F.4th at 515 (quoting *Massachusetts,* 549 U.S. at 519). The classic example of a quasi-sovereign interest is the State's "interest in the health and well-being—both physical and economic—of its residents in general." *Alfred L. Snapp & Son, Inc.,* 458 U.S. at 607. Here, the Defendants have admitted that the public health emergency definitions "operate as a predicate to action" that involves federal agencies ordering persons to quarantine for a certain period of time. 42 U.S.C. § 264(b). Those orders necessarily implicate the States' quasi-sovereign interests in both the health and economic well-being of their citizens.

Quarantine orders are designed to protect the health of citizens, and they also impose severe economic consequences on the economic well-being of state populations—at the individual and community level.<sup>7</sup> When HHS issues a quarantine order to citizens of a state, the state is preempted from issuing a separate quarantine order or countermanding the federal government's order. 42 U.S.C.

<sup>&</sup>lt;sup>7</sup> See Ben Casselman, Pandemic's Economic Impact Is Easing, but Aftershocks May Linger, THE NEW YORK TIMES, (Feb. 19, 2022), https://tinyurl.com/bdevndh6

#### Case 4:23-cv-00066-Y Document 22 Filed 05/01/23 Page 15 of 32 PageID 345

§ 264(e). And it is hard to imagine an area more squarely within the States' historic police power than actions taken to protect the health of citizens. *See Bond v. United States*, 572 U.S. 844, 854 (2014) ("The States have broad authority to enact legislation for the public good—what we have often called a 'police power.'" (citation omitted)). Moreover, this is an area the States "would likely attempt to address through [their] sovereign lawmaking powers[,]" *Texas DACA*, 50 F.4th at 515, as both have enacted laws granting state and local authorities the power to quarantine. *See* 63 O.S. § 1-504; 21 O.S. § 48-1195; Tex. Health & Safety Code § 81.001 *et seq.*; § 121.024; § 122.005-006.

Unconstitutional and unlawful delegations to international bodies in this area impede the quasi-sovereign interests of the States in the health and economic well-being of their populations. *See Texas DACA*, 50 F.4th at 516 ("The importance of immigration policy and its consequences to Texas, coupled with the restraints on Texas' power to make it, create a quasi-sovereign interest."); *Louisiana v. Becerra*, 577 F.Supp.3d 483, 492 (W.D. La 2022) ("Plaintiff States have a 'parens patriae' standing and/or a quasi-sovereign interest in protecting its citizens from being required to submit to vaccinations and/or mask mandates."). In addition, the States have proprietary interests in this litigation. The emergency definitions at issue undergird the authority of HHS to issue quarantine orders. Those orders can be issued against state employees that play instrumental roles in the state response to pandemic conditions. Furthermore, there is no apparent limitation to whom the Defendants can order to quarantine—be it governors, attorneys general, police officers, or healthcare workers. As the federal regulations restrain Oklahoma and Texas' actions in pandemic prevention, Plaintiff States possess a quasi-sovereign interest in this case. Special solicitude is merited.

#### B. Texas and Oklahoma have sufficiently pleaded injury-in-fact.

An injury in fact is "an invasion of a legally protected interest' that is 'concrete and particularized' and 'actual or imminent, not conjectural or hypothetical." *Spokeo, Inc.*, 578 U.S. at 339 (quoting *Lujan*, 504 U.S. at 560). However, the injury need not be actualized; "prospective injury" is

#### Case 4:23-cv-00066-Y Document 22 Filed 05/01/23 Page 16 of 32 PageID 346

sufficient if it "is real, immediate, and direct." *Davis v. FEC*, 554 U.S. 724, 734 (2008). A plaintiff alleges an injury-in-fact when its fear of future injury is not "imaginary or wholly speculative." *Babbitt v. United Farm Workers Nat'l Union*, 442 U.S. 289, 302 (1979). Given the special solicitude granted to States, the standards for immediacy "are easier to establish here than usual." *Texas v. United States*, 40 F.4th 205, 216 (5th Cir. 2022) ("*Texas Prioritization*"). Although "some concrete interest that is affected" is still required in this circumstance, *Summers v. Earth Island Inst.*, 555 U.S. 488, 496 (2009), "procedural rights' are special." *Lujan*, 504 U.S. at 573 n.7. For example, a person "living adjacent to the site for proposed construction of a federally licensed dam has standing to challenge the licensing agency's failure to prepare an environmental impact statement, even though he cannot establish with any certainty that the statement will cause the license to be withheld or altered, and even though the dam will not be completed for many years." *Id.* 

Texas and Oklahoma have sufficiently pleaded injury-in-fact under these precedents. During the COVID pandemic, the Defendants used their authority to order thousands of people to quarantine. Doc. 15 at 10. Based on statements from public officials and alleged health experts, a future pandemic is "almost guaranteed."<sup>8</sup> Moreover, the Defendants have admitted—even before the COVID pandemic—that they expect to issue quarantine orders yearly. *See* 82 Fed. Reg. 6916 (Jan. 19, 2017); Doc. 15 at 11. In short, this is a power that has been used and will unquestionably be used again soon. Given the widespread nature of pandemic events, Oklahomans and Texans will be among those ordered to quarantine.<sup>9</sup> And each quarantine order targeted at an Oklahoman or Texan will invade the

<sup>&</sup>lt;sup>8</sup> Joyce Hackel, *A future pandemic is 'almost guaranteed,' Fauci says*, THE WORLD (May 21, 2021), https://tinyurl.com/2p9f4zfj; *see also* Tom Frieden, *Will We Be Ready for the Next Pandemic?* THE WALL STREET JOURNAL (Feb. 12, 2021) (quoting a former head of the CDC saying the next pandemic is 'inevitable'), https://www.wsj.com/articles/will-we-be-ready-for-the-next-pandemic-11613145677. <sup>9</sup> The Defendants note that 'only Texas and Oklahoma filed this suit,'' Doc. 15 at 5 n.2, but those two States combined contain nearly 35 million people—*i.e.*, roughly 1/10th of the entire United States population. Moreover, at least one other State has expressed a desire to join this lawsuit.

#### Case 4:23-cv-00066-Y Document 22 Filed 05/01/23 Page 17 of 32 PageID 347

quasi-sovereign interests of the States. If those actions are predicated on an unconstitutional delegation to WHO of emergency decision-making, that invasion will be an unlawful harm.

The Defendants refuse to grapple with the plain meaning of the disputed regulation. See Doc. 1-3. They describe the definitions as "referring to international guidelines[,]" Doc. 15 at 1, but the only reasonable interpretation of the regulation is that it authorizes the exercise of HHS's quarantine powers. Again, the contested regulation defines the term "public health emergency." 82 Fed. Reg. 6890 (Jan. 19, 2017). And it provides five *independent* definitions for the term—*i.e.*, each definition can stand alone. 42 C.F.R. § 70.1. The final three definitions rely solely on determinations by WHO. Id. To recap, the third definition consists of "[a]ny communicable disease event ... which is notified to the World Health Organization ... as one that may constitute a Public Health Emergency of International Concern." Id. The fourth definition is met when WHO's Director-General makes a determination of a "communicable disease event" that "constitute[s] a Public Health Emergency of International Concern." Id. The fifth definition involves "[a]ny communicable disease event for which the Director-General of the [WHO] ... has issued temporary or standing recommendations for purposes of preventing ... the occurrence ... of the communicable disease." Id. The Defendants possess no control over these three definitions, which do not just refer to international guidelines. Rather, if the prescribed conditions transpire under the current regulations, a public health emergency existsregardless of any actions taken by the Defendants.

A triggering of a "public health emergency" under this regulation grants sweeping authority to the Defendants to hinder the personal liberties and well-being of individuals living in Texas and Oklahoma. As the Defendants concede, these definitions are "a predicate to action." Doc. 15 at 10; *see also* Doc. 1-3 at 3 (admission by the Defendants that "the existence of such an emergency is a statutory prerequisite to the apprehension and examination of individuals …"). The Defendants' claim that the definitions do not "authorize any action," Doc. 15 at 10, is inaccurate—as demonstrated by

#### Case 4:23-cv-00066-Y Document 22 Filed 05/01/23 Page 18 of 32 PageID 348

the Defendants' response to the Plaintiffs' petition for rulemaking. As the Defendants noted there, "Section 361(a) of the Public Health Service Act authorizes the HHS 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 States or possessions, or from one State or possession into any other State or possession." Doc. 1-3 at 1 (quoting 42 U.S.C. § 264(a)). Specifically, Section 361(b) "authoriz[es] the apprehension, detention, or conditional release of individuals." 42 U.S.C. § 264(b). But the Defendants' detention power is limited to individuals who have a communicable disease in "a communicable stage" or "a precommunicable stage, if the disease would be likely to cause a *public health emergency* if transmitted to other individuals." *Id.* § 264(d)(2) (emphasis added). Therefore, the determination of a public health emergency, per 42 C.F.R. § 70.1, authorizes the detention of citizens in Plaintiff States that are *not even in the communicable stage of a disease*. If a public health emergency already exists, then the Defendants need not make any determination that "the disease would be likely to cause" such an emergency—the work has already been done for them, by WHO, with no involvement from the United States.

Contra the Defendants, the Plaintiffs are in fact correct to assert that the regulations operate as "an automatic trigger." Doc. 15 at 11. The plain language of the regulation says so; as that regulation is written, there is no need for HHS or CDC to declare an emergency if WHO decides an emergency exists. As such, WHO's decision that a public health emergency exists in the United States means that an emergency exists for the purposes of authorizing federal mandatory quarantine orders. Other statutes that involve the official declaration of a public health emergency for other purposes would authorize the Defendants to employ other actions to protect the public from the emergency. But for the purposes of quarantine orders, if the WHO says there is a public health emergency, then there is a public health emergency in the United States.

#### Case 4:23-cv-00066-Y Document 22 Filed 05/01/23 Page 19 of 32 PageID 349

These definitions injure the quasi-sovereign interests of the States. Under the challenged regulation, a declaration by WHO that a public health emergency has occurred authorizes the Defendants to order the quarantines of any person with the specific disease—whether in the communicable or precommunicable stage. It is cold comfort that the Defendants' power is limited to people who are infected with a communicable disease in the "qualifying stage" who might move between state lines. That stage includes every person in the communicable stage and those in the precommunicable stage whose travel would be "likely to cause a public health emergency if [the disease were] transmitted to other individuals." 42 U.S.C. § 264(d). If a public health emergency has already been declared, then additional transmission by a precommunicable-stage person would necessarily cause a public health emergency. As such, a WHO declaration would trigger immense power for the Defendants and invade the Plaintiffs' interest in the health and economic well-being of their citizenry.

This injury is akin to others that have passed Article III muster. For example, the Second Circuit found that States possessed standing to challenge the denial of their rulemaking petitions "asking the NRC to reverse its 1996 Generic Environmental Impact Statement," which determined that "spent fuel pools at nuclear power plants do not create a significant environmental impact...." *New York v. U.S. Nuclear Regul. Comm'n*, 589 F.3d 551, 553 (2d Cir. 2009). The plaintiffs there grounded their standing on the fact that nuclear facilities were located in their states "and that an accident at one of these plants could harm their citizens." *Id.* The Second Circuit accepted this argument, even though it required multiple inferences. It accepted the state's standing because there were nuclear power plants near or within state borders and a chance that there will be an accident at some point. *Id.* Accordingly, the denial of the rulemaking petition could harm the States' citizens. That reasoning required no fewer "layers of speculation" than the Plaintiffs' reasoning in this case.

That the States have standing is also in line with Fifth Circuit precedent. "An increased regulatory burden typically satisfies the injury in fact requirement." *Contender Farms, L.L.P. v. U.S. Dep't* 

#### Case 4:23-cv-00066-Y Document 22 Filed 05/01/23 Page 20 of 32 PageID 350

of Agric, 779 F.3d 258, 266 (5th Cir. 2015). Here, WHO-controlled definitions of public health emergency increase the regulatory burden on the Plaintiffs by increasing the scope of authority available to the Defendants. And it is well established that federal "pressure to change state law in some substantial way" constitutes an injury-in-fact for standing. Texas v. United States, 787 F.3d 733, 749 (5th Cir. 2015) ("Texas DAPA"). This stems from the principle that "states have a sovereign interest in the power to create and enforce a legal code." Tex. Off. of Pub. Util. Counsel v. FCC, 183 F.3d 393, 449 (5th Cir. 1999) (quotation omitted). States thus "have standing to regulate matters they believe they control, to attack preemption of state laws by a federal agency, and to protect the enforcement of state law." Louisiana, 577 F.Supp.3d at 492; see also Kentucky v. Biden, 23 F.4th 585, 598 (6th Cir. 2022) ("States also have sovereign interests to sue when they believe that the federal government has intruded upon areas traditionally within states' control."). Here, the challenged regulations impede the States' abilities to use their own police powers to protect their citizens and economy from the dangers of a pandemic. More, federal quarantine orders impede their economies. See e.g., State v. Biden, 10 F.4th 538, 546-47 (5th Cir. 2021) ("Texas MPP") (Texas possessed standing in part due to the increased costs associated with an increased number of unauthorized immigrants seeking driver's licenses). Thus, the Plaintiffs have established an injury.

#### C. Texas and Oklahoma have met the other standing requirements.

Traceability requires a "personal injury fairly traceable to the defendant's allegedly unlawful conduct ...." *DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 342 (2006). Litigants with a procedural right to protect their concrete interests "can assert that right without meeting all the normal standards for redressability." *Lujan*, 504 U.S. at 572 n.7. "[W]hen a litigant is vested with a procedural right, that litigant has standing if there is some possibility that the requested relief will prompt the injury-causing party to reconsider the decision that allegedly harmed the litigant." *Massachusetts*, 549 U.S. at 518.

#### Case 4:23-cv-00066-Y Document 22 Filed 05/01/23 Page 21 of 32 PageID 351

The Plaintiffs' injuries are directly traceable to the Defendants' denial of their petition. As detailed above, the injuries stem from the unlawful delegation of authority to WHO found in the final three definitions of public health emergency in 42 C.F.R. § 70.1. Those three definitions grant WHO substantial power over the lives of Texans and Oklahomans. If it were not for those definitions, the injury would not occur. And when presented with a legitimate and straightforward petition to remove those definitions, the Defendants refused to budge. As such, the injury is fairly traceable to the Defendants' actions. As the Supreme Court has indicated, a litigant "who alleges a deprivation of a procedural protection to which he is entitled never has to prove that if he had received the procedure the substantive result would have been altered. All that is necessary is to show that the procedural step was connected to the substantive result." *Id.* at 517–518 (quoting *Sugar Cane Growers Coop. of Fla. v. Veneman*, 289 F.3d 89, 94-95 (D.C. Cir. 2002)). Here, the States' injuries are connected to the procedural step of the Defendants' decision to unlawfully reject their petition for rulemaking.

#### D. Texas and Oklahoma's case is ripe.

Ripeness is "a justiciability doctrine designed 'to prevent the courts, through the avoidance of premature adjudication, from entangling themselves in abstract disagreements over administrative policies ...." Nat'l Park Hosp. Ass'n v. Dep't of Interior, 538 U.S. 803, 807 (2003) (quoting Abbott Labs. v. Gardner, 387 U.S. 136, 148–49 (1967)). "[A] case or controversy is ripe for judicial review when an administrative decision has been formalized and its effects felt in a concrete way by the challenging parties." Tex. Indep. Producers & Royalty Owners Ass'n v. EPA, 413 F.3d 479, 483 (5th Cir. 2005) (quotation omitted). This depends primarily on two factors: whether (1) the issues are fit for judicial decision and (2) withholding a decision will cause the parties a hardship. Nat'l Park Hosp., 538 U.S. at 808. Issues are typically not ripe if they require further factual development, Anderson v. Sch. Bd. of Madison Cty., 517 F.3d 292, 296 (5th Cir. 2008), but they are generally ripe if "any remaining questions are purely legal ones." Roark & Hardee LP v. City of Austin, 522 F.3d 533, 545 (5th Cir. 2008).

#### Case 4:23-cv-00066-Y Document 22 Filed 05/01/23 Page 22 of 32 PageID 352

This is such a case. It is fit for a judicial decision, the Plaintiffs will experience hardship if a decision is not reached, and the remaining issues are not factual, but legal. The States allege that the Defendants have unlawfully delegated power to WHO and acted arbitrarily and capriciously in denying the Plaintiffs' petition for rulemaking. These claims involve the plain text of a regulation and the legality of a delegation of sovereign power to international bodies. It is hard to imagine a more quintessentially legal issue. *See e.g., Tercero v. Tex. Southmost Coll. Dist.*, 989 F.3d 291, 296 (5th Cir. 2021) ("The interpretation of a statute is a question of law...."). Moreover, the regulation is on the books and operative; it could be invoked at any time, without any more legislative or regulatory action.

It is untrue that the States' "claim rests on potential future interpretations and application of the ... definitions." Doc. 15 at 16. The definitions delegate power unlawfully to an international body *now*, and the Defendants' refusal to acknowledge this, along with their denial of the rulemaking petition, is unlawful. Little factual development is necessary. Moreover, the Plaintiffs will face hardship if they are denied a judicial decision. The regulation is not limited to a pandemic, which is part of the problem: Defendants can invoke their quarantine powers merely by WHO declaring an emergency, even if one doesn't exist. That is, under the Defendants' regulation as it is currently on the books, an international organization unaccountable to American voters could authorize quarantines entirely *absent* a pandemic, and Texas and Oklahoma would have no recourse. This Sword of Damocles could fall at any time, intruding on the States' quasi-sovereign interests in the health and well-being of their population. Thus, this case is ripe.

#### II. The Defendants' denial of the rulemaking petition was arbitrary and capricious.

The Defendants' denial of the petition for rulemaking was arbitrary and capricious in several ways. For starters, the denial was unlawful because of its unreasonable refusal to answer the States' petition for rulemaking adequately. Rather than directly respond to the States' concerns, the Defendants put their heads in the sand. Furthermore, the Defendants conceded they do not actually

#### Case 4:23-cv-00066-Y Document 22 Filed 05/01/23 Page 23 of 32 PageID 353

need the regulation. Their refusal to repeal it is therefore arbitrary and capricious. Perhaps the most fatal of the Defendants' failings is that the underlying regulation is an unlawful delegation of power to an international entity.

#### A. The Defendants' denial of the petition for rulemaking was arbitrary and capricious.

The denial of a petition for rulemaking is subject to judicial review. *Massachusetts*, 549 U.S. at 527; *see also Gulf Restoration Network v. McCarthy*, 783 F.3d 227, 234 (5th Cir. 2015) ("an agency's denial of a petition for rulemaking is 'susceptible to review""). The APA requires that agencies engage in "*reasoned* decisionmaking." *Michigan v. EPA*, 576 U.S. 743, 750 (2015) (emphasis added). Courts vacate an agency decision if the agency "has relied on factors which Congress had not intended it to consider, *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." *Nat'l Ass'n of Home Builders v. Defenders of Wildlife*, 551 U.S. 644, 658 (2007) (emphasis added) (citation omitted). If an agency errs, "[t]he reviewing court should not attempt itself to make up for such deficiencies[.]" *Motor Vehicle Mfrs. Ass'n of U.S. v. State Farm Mut. Auto. Ins.*, 463 U.S. 29, 43 (1983).

As the Supreme Court established in *State Farm*, agencies must seriously consider submitted arguments and alternative possibilities. The Court there held that the rescission of a passive restraint requirement in cars by the National Highway Traffic Safety Administration was arbitrary and capricious because the agency "gave no consideration whatever" to implementing an alternative standard, as opposed to wholesale rescission of the standard. *Id.* at 46. Similarly, a response to a petition for rulemaking must "clearly indicate that [the agency] has considered the potential problem identified in the petition" and is arbitrary and capricious if it "entirely failed to consider an important aspect of the problem." *Compassion Over Killing v. U.S. FDA*, 849 F.3d 849, 857 (9th Cir. 2017) (citing *Massachusetts*, 549 U.S. at 533).

#### Case 4:23-cv-00066-Y Document 22 Filed 05/01/23 Page 24 of 32 PageID 354

Here, by refusing to acknowledge what the regulatory definitions actually say and mean, the Defendants failed to consider an important aspect of the problem—namely, that the contested definitions are an unlawful delegation of authority. The States' primary complaint with the regulations is that they "permit[] the WHO to determine when a public health emergency exists." Doc. 1-2 at 8. The Defendants ignored this point—the point that underlies the entire petition and complaint. By not considering the text of the regulation, the Defendants refused to grapple with the implications of granting WHO the ability to declare a public health emergency under American law, thereby refusing to address in any meaningful way the legality of the Defendants' delegating sovereign authority to an international organization.

Instead, the Defendants' response effectively conceded that the definitions of "public health emergency" define the contours of their quarantine power, stating that the definitions "provide the public with a clear understanding of HHS/CDC's authority for interstate quarantine, isolation, or conditional release." Doc. 1-3 at 2. The Defendants further admitted that the term "public health emergency' ... authorizes specific public health measures (apprehension and examination) to specific individuals ... but only if the disease would be likely to cause a public health emergency." *Id.* at 2–3 (citing 82 Fed. Reg. 6905 Jan. 19, 2017). In other words, the existence of a public health emergency "is a statutory prerequisite" for the Defendants' authority to issue quarantine orders to individuals in the precommunicable stage of a quarantinable communicable disease. *Id.* at 3. It is therefore true that if the conditions for the statutorily defined public health emergency are met, a public health emergency exists and the statutory prerequisite for the Defendants' exercise of their quarantine power has occurred. In sum, a determination by WHO that a public health emergency exists triggers immense federal power *without deliberation by politically accountable actors*. And rather than grapple with that reality, the Defendants admitted that one reason they refuse to consider repealing the regulations is because they want to make WHO even stronger.

#### Case 4:23-cv-00066-Y Document 22 Filed 05/01/23 Page 25 of 32 PageID 355

The Defendants' response did not address what the regulation actually does. It instead sidestepped the regulation's plain text, insisting that "CDC would only consider WHO's determinations when exercising its own independent judgment regarding apprehension and detention of individuals." *Id.* It also pointed to instances where HHS/CDC allegedly exercised their judgment to require citizens to quarantine. *Id.* at 3-4. Neither of those answers the States' petition. The States do not claim that the Defendants can never exercise discretion in choosing when to issue a quarantine order. Rather, they merely point out that three of the independent definitions of "public health emergency" allow WHO and its member nations to unilaterally trigger significant power for the Defendants. The Defendants' response left this point unanswered. The Defendants' retort boils down to, "just trust us—we won't abuse this unlawful regulation." This is arbitrary and capricious.

Even now, the Defendants dance around the regulation's clear meaning. They describe the definitions as merely "referring to international guidelines issued by organizations like the [WHO]," Doc. 15 at 1; claim the definitions simply make "references to WHO," *id.* at 4, 19; and state that they merely "assist HHS in determining whether a public health emergency from a communicable disease actually exists[,]" *id.* at 10. Each of these is just a shuffle-step to skirt the plain language of the regulations. As previously explained, the definitions use the disjunctive "or," which means that each definition is sufficient by itself to establish that a public health emergency is present. 42 C.F.R. § 70.1. A WHO determination that a public health emergency exists in the United States means that a public health emergency exists for the purposes of 42 C.F.R. § 70.1. It doesn't "assist"—it makes it reality. At no point have the Defendants addressed this problem. They instead try to avoid it, emphasizing that other statutes "provide discretionary authority to HHS/CDC to take action." Doc. 15 at 12. But these citations only underscore that Congress wanted the Defendants to exercise their power using solely their *own* discretion—not WHO's. The definitions, to the extent that they grant authority to the Defendants based on a WHO declaration, are inconsistent with the statutes passed by Congress to

#### Case 4:23-cv-00066-Y Document 22 Filed 05/01/23 Page 26 of 32 PageID 356

govern the federal government's response to a pandemic, none of which delegates federal authority to WHO. Because the Defendants' denial of the petition for rulemaking failed to "consider[] the potential problem identified in the petition," the denial was arbitrary and capricious.

The Defendants' response also insisted that even if repealing the definitions wouldn't cause them any harm it was not worth "the expenditure of agency resources" to do so. Doc. 1-3 at 6. The Defendants cannot have it both ways. If definitions add nothing to the regulation, they should be repealed so they aren't used to read in a meaning that doesn't exist. *Cf. TRW Inc. v. Andrews*, 534 U.S. 19, 31 (2001) ("It is 'a cardinal principle of ... statutory construction' that 'a statute ought, upon the whole, to be so construed that, if it can be prevented, no clause, sentence, or word shall be superfluous, void, or insignificant."" (citation omitted)). If they unlawfully increase the scope of agency authority, they should be amended. Either way, "it's not worth our time" is no justification for refusing to repeal the definitions—and they certainly have not established that either amendment or repeal would be too burdensome.

When faced with a similar situation where a federal agency misconstrued the meaning of a petition for rehearing, the D.C. Circuit chose to remand the petition for a response that adequately considered the problems presented by the petition. *See NAACP v. Fed. Power Comm'n*, 520 F.2d 432, 447 (D.C. Cir. 1975). This Court could do the same here. At a bare minimum, the motion to dismiss should be denied.

#### B. The challenged definitions violate the delegation doctrine.

"The fundamental precept of the delegation doctrine is that the lawmaking function belongs to Congress and may not be conveyed to another branch or entity." *Loving v. United States*, 517 U.S. 748, 758 (1996) (citing U.S. CONST., art. I, § 1; *Field v. Clark*, 143 U.S. 649, 692 (1892)). No agency has any inherent power to make law, and "an agency literally has no power to act ... unless and until Congress confers power upon it." *La. Pub. Serv. Comm'n v. FCC*, 476 U.S. 355, 374 (1986). "It is well

#### Case 4:23-cv-00066-Y Document 22 Filed 05/01/23 Page 27 of 32 PageID 357

established that Congress may, by a legislative act, grant authority to an executive agency ... to adopt rules and regulations, so long as it provides some 'intelligible principle' by which the agency is to exercise that authority." *Perot v. FEC*, 97 F.3d 553, 559 (D.C. Cir. 1996) (quoting *Mistretta v. United States*, 488 U.S. 361, 372 (1989)). Here, Congress never delegated any authority at all for WHO to make public health emergency determinations.

#### 1. <u>The definitions are unlawful because the Defendants lack specific</u> <u>authorization from Congress.</u>

Congress never delegated any authority for WHO to make public health emergency determinations. A congressional delegation of authority to an executive agency does not carry with it the power to further subdelegate that authority to outside parties. "Agencies may play the sorcerer's apprentice but not the sorcerer himself." *Alexander v. Sandoval*, 532 U.S. 275, 291 (2001). "[W]hile federal agency officials may subdelegate their decision-making authority to subordinates absent evidence of contrary congressional intent, they may not subdelegate to outside entities—private or sovereign—absent affirmative evidence of authority to do so." *U.S. Telecom Ass'n v. FCC*, 359 F.3d 554, 566 (D.C. Cir. 2004) (emphasis added); *see also Perot*, 97 F.3d at 559 ("[W]hen Congress has specifically vested an agency with the authority to administer a statute, it may not shift that responsibility to a private actor."). This principle still holds even though the United States is a member of WHO. "The United States' membership in the WHO does not transform the WHO into a federal entity...," *Children's Health Def. v. Facebook Inc.*, 546 F. Supp. 3d 909, 927 n.7 (N.D. Cal. 2021).

The prohibition against delegation to outside parties "is entirely sensible [because]... when an agency delegates power to outside parties, lines of accountability may blur, undermining an important democratic check on government decision-making." *U.S. Telecom Ass'n*, 359 F.3d at 565. Additionally, "delegation to outside entities increases the risk that these parties will not share the agency's national vision and perspective, and thus may pursue goals inconsistent with those of the agency and the

#### Case 4:23-cv-00066-Y Document 22 Filed 05/01/23 Page 28 of 32 PageID 358

underlying statutory scheme." *Id.* at 565-66 (quotation omitted). As such, "subdelegations to outside parties are assumed to be improper absent an affirmative showing of congressional authorization." *Id.* at 565.

The final rule adopting the definitions claimed 42 U.S.C. § 264(d)(2)(B) as statutory justification. 82 Fed. Reg. 6,890, 6,891 (Jan. 19. 2017). Nothing in Section 264 authorizes subdelegation to outside entities in general or to WHO specifically. Nor do the Defendants point to any other statutory authorization for the definitions' sub-delegation to WHO. The definitions are thus presumptively improper.

# 2. <u>The definitions are unlawful because the Defendants exercise no 'meaningful</u> <u>oversight' WHO.</u>

A sub-delegation to an outside entity is only permissible if the agency has "meaningful oversight" over the external entity. *See Nat'l Horsemen's Benevolent & Protective Ass'n v. Black*, 53 F.4th 869, 872 (5th Cir. 2022). An agency lacks "meaningful oversight if it does not write the rules, cannot change them, and cannot second-guess their substance." *Id.* The Defendants have none of these powers over the WHO and thus exercise no "meaningful oversight" at all.

As discussed above, the Defendants attempt to argue around the obvious delegation issues by claiming "[t]he three definitions ... merely identify when an international organization believes a public health emergency exists as something HHS or the CDC may, but need not, consider." Doc. 15 at 22. But again, a plain reading of the regulation shows precisely the opposite. None of the three definitions grant any discretion at all to HHS or the CDC. Rather, they each independently and automatically trigger a public health emergency.<sup>10</sup> Because each definition acts independently, if any one of the

<sup>&</sup>lt;sup>10</sup> *Cf., e.g., United States v. Woods*, 571 U.S. 31, 46 (2013) (disjunctive list means that the listed "items are alternatives"); *United States v. Schmidt*, 623 F.3d 257, 265 (5th Cir. 2010), *as revised* (Oct. 22, 2010) (in statutory list of "three disjunctive prongs, ... any one of which" is sufficient to trigger applicability (emphasis added)); *Sidag Aktiengesellschaft v. Smoked Foods Products Co.*, 960 F.2d 564, 566 (5th Cir. 1992) ("an affirmative finding that any one of ... five ... characteristics" in disjunctive list "would

#### Case 4:23-cv-00066-Y Document 22 Filed 05/01/23 Page 29 of 32 PageID 359

definitions allows for a public health emergency to be triggered without "meaningful oversight" from the Defendants, then that definition violates the delegation doctrine. Neither definitions (3), (4), nor (5) allow for any "meaningful oversight." All three definitions, therefore, are unlawful.

Diving in deeper, definition (3) says that a public health emergency means "[a]ny communicable disease event the occurrence of which is notified to the [WHO], in accordance with Articles 6 and 7 of the International Health Regulations, as one that may constitute a Public Health Emergency of International Concern." 42 C.F.R. § 70.1. Articles 6 and 7 of the International Health Regulations ("IHR") require "[e]ach State Party" of WHO to "notify WHO ... of all events which may constitute a public health emergency of international concern."<sup>11</sup> Definition (3) says nothing about allowing the Director of the CDC, the HHS Secretary, or any other U.S. government official to exercise any discretion. In fact, it doesn't mention them at all. Nor do Articles 6 and 7 of the IHR. Thus, under definition (3), whenever a WHO member state notifies the WHO of a "Public Health Emergency of International Concern" under Articles 6 and 7 of the IHR, then definition (3) automatically triggers a public health emergency under U.S. law without oversight of any kind from any agency, officer, or employee of the U.S government.

Under definition (4), an emergency is triggered by "[a]ny communicable disease event the occurrence of which is determined by the Director-General of the World Health Organization, in accordance with Article 12 of the [IHR]." 42 C.F.R. § 70.1. Article 12 of the IHR sets forth the procedures under which the WHO Director-General may make a "[d]etermination of a public health emergency of international concern."<sup>12</sup> As with definition (3), definition (4) allows for no discretion to be exercised by any U.S. government official, and neither does Article 12 of the IHR.

suffice to trigger"); United States v. Brockway, 769 F.2d 263, 265 (5th Cir. 1985) (in a disjunctive list, "any one or more of the stated objectives will suffice").

 <sup>&</sup>lt;sup>11</sup> WHO, International Health Regulations 12, Art. 6 (3d ed. 2005), https://tinyurl.com/bdhmp49a.
<sup>12</sup> WHO, Int'l Health Regulations 14, Art. 12 (3d Ed. 2005), https://tinyurl.com/bdhmp49a.

#### Case 4:23-cv-00066-Y Document 22 Filed 05/01/23 Page 30 of 32 PageID 360

Under definition (5), a public health emergency is triggered by "[a]ny communicable disease event for which the Director-General of the [WHO], in accordance with Articles 15 or 16 of the [IHR], has issued temporary or standing recommendations for purposes of preventing or promptly detecting the occurrence or reoccurrence of the communicable disease." 42 C.F.R. § 70.1. Articles 15 and 16 of the IHR set forth the procedures for the Director-General to issue temporary or standing recommendations to address "a public health emergency of international concern."<sup>13</sup> As with definitions (3) and (4), there is no provision in definition (5) or in Articles 15 and 16 of the IHR for any U.S. government official to exercise discretion—the WHO Director-General's issuance of temporary or standing recommendations automatically triggers the public health emergency.

#### 3. <u>The Defendants mischaracterize the three definitions as discretionary.</u>

The Defendants claim that the definitions merely state that HHS will be able to consider "multiple organizations' (or officials') views of a public health emergency ... when deciding whether to take discretionary action." Doc. 15 at 21. However, in light of the definitions' plain language, the Defendants' characterization makes no logical sense.

Definitions (1) and (2) already empower the CDC Director and HHS Secretary to determine when there is a public health emergency. These first two definitions do not in any way constrain whom the Secretary or Director may consult when making a public health emergency determination. In other words, definitions (1) and (2) already confer on the Secretary and the Director the power to consult with WHO. If definitions (3) through (5) really did only mean that the Secretary and Director may permissively consider (or not) WHO's determinations, then it raises the question: Why bother including definitions (3) through (5) at all?

<sup>&</sup>lt;sup>13</sup> WHO, Int'l Health Regulations 14, Art. 15 & 16 (3d Ed. 2005), https://tinyurl.com/bdhmp49a.

#### Case 4:23-cv-00066-Y Document 22 Filed 05/01/23 Page 31 of 32 PageID 361

If the last three definitions really are just discretionary "mays" that are merely descriptive of things the Secretary or Director might consider (or not), then they are entirely superfluous and contradict the basic principle of constitution that demands avoiding surplusage. *See, e.g., TRW*, 534 U.S. at 31. The Defendants' proffered interpretation would render definitions (3) through (5) entirely redundant and violate the canon against surplusage three separate times in a single subsection of a single regulation. Because definitions (3) through (5) mean what they say, they unlawfully delegate authority to WHO to determine when a public health emergency exists.

#### **CONCLUSION**

For the foregoing reasons, the Court should deny the Defendants' motion to dismiss.

#### Respectfully Submitted,

s/ Zach West

ZACH WEST Director of Special Litigation AUDREY A. WEAVER Assistant Solicitor General OKLAHOMA ATTORNEY GENERAL'S OFFICE 313 NE 21st Street Oklahoma City, OK 73105 Phone: (405) 521-3921 Zach.West@oag.ok.gov Audrey.Weaver@oag.ok.gov Counsel for Plaintiff State of Oklahoma

and

AARON F. REITZ *Lead Counsel* Deputy Attorney General for Legal Strategy Texas Bar No. 24105704 aaron.reitz@oag.texas.gov GRANT DORFMAN Deputy First Assistant Attorney General Texas Bar No. 00783976 grant.dorfman@oag.texas.gov

GENE P. HAMILTON America First Legal Foundation

300 Independence Avenue SE Washington, DC 20003 (202) 964-3721 gene.hamilton@aflegal.org *Counsel for Plaintiff State of Texas* 

## **CERTIFICATE OF SERVICE**

I hereby certify that on this 1<sup>st</sup> day of May, 2023, I electronically transmitted the foregoing document to the Clerk of Court using the ECF System for filing and transmittal of a Notice of Electronic Filing to the ECF registrants with entries of appearance filed of record.

*s/ Zach West* ZACH WEST