

**United States District Court
Northern District of Texas
Fort Worth Division**

STATE OF TEXAS,

STATE OF OKLAHOMA,

Plaintiffs,

v.

Case No:

U.S. DEPARTMENT OF HEALTH AND HUMAN
SERVICES,

XAVIER BECERRA, in his official capacity
as Secretary of Health and Human
Services,

MARVIN FIGUEROA, in his official capacity
as Director of Intergovernmental and
External Affairs of the Department of
Health and Human Services,

Defendants.

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

I. INTRODUCTION

1. The United States Department of Health and Human Services and its officials have unlawfully denied a petition to remove an unlawful regulation from federal law.

2. The Department's definition of "public health emergency" in 42 C.F.R. § 70.1 exceeds the agency's authority, as it unlawfully delegates to the World Health Organization (WHO) the authority to invoke emergency health powers in the United States—infringing on U.S. and state sovereignty.

3. The Plaintiffs requested repeal of this unlawful rule through a petition for rulemaking brought under the Administrative Procedure Act (APA). The Defendants rejected the petition, and in so doing, did not provide a rational explanation for keeping an unlawful regulation in federal law. Accordingly, the Defendants' denial of the petition is arbitrary and capricious.

4. This Court should either (a) issue declaratory and injunctive relief against the plainly unlawful delegation of power to a foreign entity, or (b) provide injunctive relief granting the petition for rulemaking. At a minimum, the Defendants unlawfully withheld an adequate response to the Petition. This Court should therefore declare the plain meaning of the regulation and remand the Petition for a meaningful response on the regulation at issue.

II. JURISDICTION AND VENUE

5. Jurisdiction is proper in this United States District Court under 28 U.S.C. §§ 1331, 1346, 2201, 2202, and 2241.

6. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(e) because at least one Plaintiff resides here.

III. PARTIES

7. Plaintiff State of Oklahoma is a sovereign state. Its legal interests are represented by the Attorney General of Oklahoma, who submitted the petition for rulemaking at issue in this case.

8. Plaintiff State of Texas is a sovereign state. Its legal interests are represented by the Attorney General of Texas, who signed the petition for rulemaking at issue in this case.

9. Defendant United States Department of Health and Human Services is an agency of the United States. HHS received and responded to the petition for rulemaking at issue in this case.

10. Defendant Xavier Becerra is the Secretary of Health and Human Services. He received the petition for rulemaking, and the response was submitted on his behalf.

11. Defendant Marvin Figueroa is the Director of Intergovernmental and External Affairs of the Department of Health and Human Services. He responded to the petition for rulemaking on behalf of Defendant HHS and Defendant Secretary Becerra.

IV. BACKGROUND

The Regulation

12. HHS has the authority to enact rules to “prevent the introduction, transmission, or spread of communicable diseases” either from foreign countries into the United States or between the states themselves. 42 U.S.C. § 264(a).

13. When enforcing these rules, HHS may inspect, alter, or destroy animals or articles found to be sources of dangerous infection. *Id.* In addition, HHS may provide for the apprehension and examination of individuals in certain infected states. *Id.* § 264(d). Upon recommendation of the HHS Secretary, the President of the United States may also authorize the detention of individuals under certain circumstances. *Id.* § 264(b).

14. On January 19, 2017, one day before President Barack Obama’s second term expired, HHS promulgated a rule defining the term “public health emergency.” *See* 82 Fed. Reg. 6890 (Jan 19, 2017). It provided five definitions for the term:

i. The first definition relies on determinations of the Director of the Centers for Disease Control and Prevention (CDC). A “public health emergency” is “(1) Any communicable disease event as determined by the [CDC] Director with either documented or significant potential for regional, national, or international communicable disease spread or that is highly likely to cause death or serious illness if not properly controlled.” 42 C.F.R. § 70.1.

ii. The second definition relies on determinations of the Defendant Secretary. A “public health emergency” is “(2) Any communicable disease event

described in a declaration by the Secretary pursuant to 319(a) of the Public Health Service Act (42 U.S.C. 247d (a)).” 42 C.F.R. § 70.1.

iii. The final three definitions rely solely on information from, and determinations by, the WHO. A “public health emergency” according to those WHO determinations 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;¹ 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 International Health Regulations [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 International Health Regulations, 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.

15. In 2017, when responding to public comments criticizing this approach as a breach of United States sovereignty, HHS argued that it would not actually use definitions (3), (4), and (5) of public health emergency. 82 Fed. Reg. 6890, 6905-06.

¹ The IHR define “public health emergency of international concern” as “an extraordinary event which is determined, as provided in these Regulations: (i) to constitute a public health risk to other States through the international spread of disease and (ii) to potentially require a coordinated international response.” IHR, art. 1.

Instead, HHS insisted that it “will continue to make its own independent decisions regarding” public health emergencies. *See id.* at 6906.

16. Contradicting HHS’s responses, the plain text of the rules purports to confer authority on HHS to rely solely on determinations by the WHO, rather than making independent decisions. Indeed, HHS admitted in 2017 that the declaration by the WHO or notification to the WHO of a Public Health Emergency of International Concern is a “way for HHS/CDC to define when the precommunicable stage of a quarantinable communicable disease may be likely to cause a public health emergency if transmitted to other individuals.” *Id.* at 6905. Then, despite disclaiming any need to use definitions (3), (4), and (5) of public health emergency, HHS proceeded to finalize a rule containing those very definitions, without change or alteration.

The Petition for Rulemaking

17. The Plaintiffs oppose the unlawful regulation because it encroaches on their reserved powers, authority, and sovereignty.

18. The Plaintiffs are sovereign states. Because the Plaintiffs retain all sovereignty not delegated to the federal government, *see* U.S. Const. amend. X, the Plaintiffs have an interest in any action of the federal government that might unduly encroach on Plaintiffs’ reserved police powers.

19. The applicable statute for public health emergencies asserts that the exercise of federal authority preempts conflicting State laws. 42 U.S.C. § 264(e). The Plaintiffs seek to protect the applicability of their health and safety laws against unlawful preemption by the actions of federal officials.

20. The federal statute and regulations also permit the federal government to encroach on State property and detain State personnel in public health emergencies. The Plaintiffs seek to protect their property and personnel against unlawful action or delegation by federal officials.

21. The statute and regulations for public health emergencies also potentially permit the federal government to encroach on the property or person of the Plaintiffs' citizens.

22. The Plaintiffs seek to protect their quasi-sovereign interest in the health and well-being of their residents against unlawfully intrusive action delegation by federal officials. *See Alfred L. Snapp & Son, Inc. v. Puerto Rico, ex rel., Barez*, 458 U.S. 592, 607 (1982).

23. In furtherance of these interests, the Plaintiffs filed a petition for rulemaking with Defendant HHS and Defendant Secretary. *See* Ex. 1. The petition requested the deletion of definitions (3), (4), and (5) of public health emergency in 42 C.F.R. § 70.1. *See id.*

24. The petition asserted three bases for the requested rulemaking. *See id.* *First*, the existing definitions exceed HHS's authority by unlawfully delegating their decisions to foreign nations or international organizations, absent express permission from Congress. *See id.* *Second*, changed circumstances justify further rulemaking because events since the adoption of the regulation in 2017 demonstrate that the WHO allows political factors to influence its health determinations. *See id.* In particular, the WHO was undeniably subject to politically based manipulation in its

handling of the COVID pandemic, making it a particularly untrustworthy repository for delegation of United States sovereignty. *See id.* *Third*, rulemaking is appropriate because HHS has openly denied that it needs to use the unlawful rules as written, and leaving the regulation in place therefore threatens State interests without advancing any current federal interest. *See id.*

The Response to the Petition

25. On October 31, 2022, the Defendants denied the Plaintiffs’ petition for rulemaking in a response letter. *See Ex. 2.*

26. After some statutory and regulatory background, the Defendants first re-asserted their position that HHS “will continue to make its own independent decisions” and will only “give consideration” to information from the WHO. *Id.* at 3. The Defendants provided examples to confirm that HHS has exercised independent judgment over the past few years. *Id.* at 3-4.

27. Next, the Defendants asserted that it is nevertheless “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.

28. As stated in the petition, HHS’s position that definitions (3), (4), and (5) merely inform the public of sources consulted is not a plausible reading of the text of the regulation. *See Ex. 1* at 3 ¶ 6. The plain text defines “public health emergency” to include “[a]ny communicable disease event” that is “determined by the Director-General of the World Health Organization” as meeting certain criteria or is “notified to the World Health Organization” by a member. 42 CFR § 70.1. Recasting that text

as merely a source list for CDC or HHS decision-making ignores the plain meaning of that text.

29. The Defendants did not address this plain meaning point even though it was raised in the petition, nor did they otherwise address why the Plaintiffs' reading of the regulation is incorrect. *See generally* Ex. 2.

30. The Defendants instead assumed, without explaining, the implausible reading of the regulation in order to avoid addressing the problems raised in the petition.

31. In particular, the Defendants did not explain why influencing the WHO requires deferring to the WHO's unilateral decision-making process. *See id.* Instead, the Defendants appear to assume that the regulation does not delegate any decisions to the WHO in order to analyze why regulatory changes are unnecessary. *See id.*

32. Significantly, the Defendants did not dispute the Plaintiffs' charge that political influence is warping the WHO's analysis, but instead emphasized the importance of "strengthening WHO" from its current status. *See* Ex. 2 at 4. The Defendants then discussed the history and value of the International Health Regulations. *See id.* at 4-5.

33. At the end, the Defendants asserted, remarkably, that deleting or amending regulations that HHS does not currently use is not worth "the expenditure of agency resources." *Id.* The Defendants also offered no plausible explanation why agency resources should be spent adopting unlawful or unnecessary regulations but should not be spent repealing unlawful or unnecessary regulations.

34. Because the Defendants have effectively conceded that the WHO needs changes to be reliable and should not be a sole source of authority or power, the disputes between the Plaintiffs and the Defendants are (1) whether the regulation is unlawful, and (2) whether the regulation should be repealed when it threatens state interests without advancing federal interests.

V. CLAIMS FOR RELIEF

COUNT ONE: UNLAWFUL AND UNREASONABLE REFUSAL TO ADEQUATELY ANSWER A PETITION FOR RULEMAKING— 5 U.S.C. §§ 553(E), 706

35. The Plaintiffs adopt and incorporate by reference all preceding allegations.

36. When given their plain meaning, definitions (3), (4), and (5) of public health emergency 42 C.F.R. § 70.1 are unlawful delegations of United States and/or state authority to foreign nations or international organizations.

37. Definition (1) of public health emergency in 42 C.F.R. § 70.1 is the sole definition of that term that refers to a decision of the CDC Director.

38. Definition (2) of public health emergency in 42 C.F.R. § 70.1 is the sole definition of that term that refers to a decision of the Defendant Secretary.

39. Definition (3) of public health emergency in 42 C.F.R. § 70.1 defers to communicable disease events notified to the WHO and does not refer to a decision of the CDC Director or the Defendant Secretary.

40. Definition (4) of public health emergency in 42 C.F.R. § 70.1 defers to a determination of the Director of the WHO and does not refer to a decision of the CDC Director or the Defendant Secretary.

41. Definition (5) of public health emergency in 42 C.F.R. § 70.1 defers to a decision of the Director of the WHO and does not refer to a decision of the CDC Director or the Defendant Secretary.

42. The Defendants' response to the Plaintiffs' petition denies and ignores the plain meaning of the regulation at issue.

43. The Defendants' failure to accurately address the law at issue renders their decision unlawful within the meaning of the APA. *See* 5 U.S.C. § 706.

44. A response to a petition for rulemaking must "clearly indicate that it 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. Food & Drug Admin.*, 849 F.3d 849, 857 (9th Cir. 2017).

45. The Defendants cannot meaningfully address the legality of delegations of authority to foreign nations or international organizations without first admitting that those delegations occur by the plain import of the regulation in question.

46. Where the response to a petition for rulemaking misstates the law, the proper remedy is for the Court to declare what the law is and remand the petition for a response that adequately considers the problems presented by the petition. *See*

Nat'l Ass'n for Advancement of Colored People v. Fed. Power Comm'n, 520 F.2d 432, 446 (D.C. Cir. 1975).

**COUNT TWO: ARBITRARY AND CAPRICIOUS REFUSAL TO REPEAL AN
UNLAWFUL REGULATION—
5 U.S.C. §§ 553(E), 706**

47. The Plaintiffs adopt and incorporate by reference all preceding allegations.

48. The Constitution prohibits all federal agencies, including HHS, from delegating their decisions to foreign nations or international organizations absent express provision or permission from Congress. *See, e.g., Defs. of Wildlife v. Gutierrez*, 532 F.3d 913, 926 (D.C. Cir. 2008).

49. Here, there is no treaty or international agreement that calls for or requires delegation like that present in the challenged regulation. Even if there were such a treaty, Congress would need to implement such a treaty through the statutory process. Because Congress has not authorized delegating declarations of public health emergencies to the WHO, HHS has exceeded its authority by promulgating rules that make just such a delegation.

50. These limits matter because unlawful delegations outside the federal government undermine accountability for executive decisions. When federal officers make executive decisions, the President can hold officers responsible for those decisions, and voters can in turn hold the President responsible for those decisions. Delegating the decision outside the executive branch allows the President and his officers to disclaim responsibility for important policy decisions, effectively

rendering the key decisionmakers beyond the reach of the voting public. In contrast, keeping decisions regarding public health emergencies with HHS and not the WHO allows voters to continue having a say in whether officials are wisely using their authority.

51. While delegation to any outside group is unlawful, delegating decisions to a foreign or international organization causes particular harm to the sovereignty of both the United States and the Plaintiffs.

52. A core aspect of sovereignty is that the authority to govern is derived from the people governed. The Federalist No. 46, at 294 (James Madison) (Clinton Rossiter ed., 1961). The federal government and the states can share sovereignty because their authority derives from the same people. Delegations to groups inside the United States inappropriately rebalance the authority that the American people have conferred, and delegations outside the United States inappropriately seek to strip authority from the people entirely.

53. By allowing the WHO to determine when a public health emergency exists, transferred police power to an international organization, assigning the sovereign police power outside the constitutional order. This delegation of authority not only violates nondelegation principles but also infringes state sovereignty, as states would otherwise retain a wide range of police powers to address public health emergencies subject only to congressional action. *See Kelly v. Washington*, 302 U.S. 1, 9–10 (1937); *accord Breard v. City of Alexandria*, 341 U.S. 622, 634 (1951) (emphasizing state power cited in *Kelly*). Allowing an international organization to

determine when public health emergencies exist *in the United States* necessarily allows that organization to use or authorize the use of police powers that were neither given to it or to the federal government by the states.

54. Definition (3) of “public health emergency,” which defers to any communicable disease event reported to the WHO, *see* 42 C.F.R. § 70.1, is a direct affront to the sovereignty of the U.S. government and the States. Definition (3) delegates some authority to the WHO by referring to reportable events under the IHR, and it further delegates authority to WHO member nations who make reports under those regulations. A foreign nation’s decision to report a novel strain of influenza is not remotely contemplated as a public health emergency in U.S. statutes, and delegating our sovereign decisions to those foreign nations making reports is a quintessential and outlandish violation of both State and federal sovereignty.

55. Nothing in any federal statute forbids the Surgeon General or the Secretary from considering information from the WHO as part of exercising their judgment. Nevertheless, “[a]n agency may not . . . merely ‘rubber-stamp’ decisions made by others under the guise of seeking their ‘advice,’ nor will vague or inadequate assertions of final reviewing authority save an unlawful subdelegation.” *U.S. Telecom Ass’n v. F.C.C.*, 359 F.3d 554, 568 (D.C. Cir. 2004) (internal citations omitted). As a result, definitions (3), (4), and (5) are problematic because their plain text allows the delegation of determinations of a public health emergency to the WHO and to WHO member nations.

56. Accordingly, although HHS may consider the WHO's views, the determination of a public health emergency should occur under HHS's judgment, and definitions (3), (4), and (5) of a public health emergency should be repealed as unlawful.

57. HHS has not articulated any reason to retain an unlawful regulation.

58. An agency cannot merely refer to past answers when denying a petition for rulemaking involving changed circumstances. *See Midwest Indep. Transmission Sys. Operator, Inc. v. FERC*, 388 F.3d 903, 913 (D.C. Cir. 2004). HHS's tacit admission that circumstances have changed since 2017 and that the WHO now needs strengthening to be trustworthy indicate that the delegations are not as defensible now as they were in 2017.

59. By failing to articulate why the delegations are lawful, HHS has arbitrarily and capriciously denied a petition to remove those delegations from federal regulations.

**COUNT THREE: ARBITRARY AND CAPRICIOUS REFUSAL TO REPEAL
A REGULATION THAT HHS CONCEDES IT DOES NOT NEED—
5 U.S.C. §§ 553(E), 706**

60. The Plaintiffs adopt and incorporate by reference all preceding allegations.

61. HHS has openly admitted it does not intend to use definitions (3), (4), and (5) of public health emergency in 42 C.F.R. § 70.1.

62. HHS's and CDC's independent decisions would continue to be cognizable under definitions (1) and (2) were the Defendants to repeal the other definitions.

63. Retaining definitions (3), (4), and (5) serves no legitimate federal governmental purpose if those definitions are truly unnecessary.

64. Declining to repeal an unlawful regulation because of the time, effort, and burden it might take to initiate such a repeal is not a valid reason to avoid repealing a regulation; otherwise, no regulation would ever be repealed.

65. Retaining definitions (3), (4), and (5) could serve the purpose of permitting a future HHS to change its views on the WHO without notice and comment. By including the additional definitions deferring to the WHO, HHS is facilitating complete deferral to the WHO in the future even if it professes no intent to defer to WHO now.

66. HHS's decision to include definitions of public health emergency that serve no federal purpose but threaten State interests was an arbitrary and capricious decision because there is no explanation or rationale for those definitions.

COUNT FOUR: VIOLATION OF THE U.S. CONSTITUTION (NON-DELEGATION)

67. The Plaintiffs adopt and incorporate by reference all preceding allegations.

68. The U.S. Constitution vests all legislative power in Congress and all executive power in the President. U.S. Const. art. I, § 1, cl. 1; *id.* art. II, § 1, cl. 1

69. Agencies “may not subdelegate to outside entities—private or sovereign—absent affirmative evidence of authority to do so.” *Defenders of Wildlife*, 532 F.3d at 927.

70. The WHO is an outside entity.

71. The member nations of the WHO other than the United States are outside entities.

72. No statute authorizes the Defendants to delegate decisions regarding public health emergencies to the WHO or to members of the WHO.

73. Construing any general authority over public health to silently authorize such delegations would unlawfully commit a major policy decision to agencies instead of to Congress. Courts “presume that Congress intends to make major policy decisions itself, not leave those decisions to agencies.” *W. Virginia v. Evtl. Prot. Agency*, 142 S. Ct. 2587, 2609 (2022) (internal quotation marks and citation omitted). Even if HHS has “a colorable textual basis” or a “merely plausible textual basis” for its definitions, it cannot enact major policy changes without demonstrating “clear congressional authorization” for the power it claims. *Id.*

74. The Defendants have objected to taking the time necessary to repeal these unlawful rules. *See Ex. 2* at 6.

75. Direct declaratory and injunctive relief from this Court would remedy the States’ harm without compelling the agency to engage in rulemaking.

VI. PRAYER FOR RELIEF

For these reasons, the Plaintiffs respectfully request the following relief:

- a) A declaration that the plain text of definitions (4) and (5) of public health emergency in 42 C.F.R. § 70.1 authorizes agency action based solely on decisions of the Director of the WHO;
- b) A declaration that the plain text of definition (3) of public health emergency in 42 C.F.R. § 70.1 authorizes agency action based solely on decisions of WHO member states;
- c) A declaration that those definitions are unlawful delegations of authority to outside entities;
- d) Injunctive relief setting aside the unlawful definitions;
- e) Alternatively, injunctive relief granting the petition for rulemaking;
- f) Alternatively, a remand for an adequate response to the petition based on those declarations;
- g) A judgment for costs as appropriate under 28 U.S.C. § 2412; and
- h) Such other relief as the Court may deem just and proper.

Dated: January 18, 2023

Respectfully Submitted,

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*** Application for admission forthcoming.