United States District Court
Northern District of Texas
Fort Worth Division

STATE OF TEXAS,

STATE OF OKLAHOMA,

Plaintiffs,

v.

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.

Case No:

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. Envtl. 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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Solicitor General

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*** Application for admission forthcoming.

CIVIL COVER SHEET

Case 4:23-cv-00066-Y Document 1-1 Filed 01/18/23 Page 1 of 2 PageID 20

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

State of Texas, State of Oklahoma

(b) County of Residence of First Listed Plaintiff N/A
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*

Aaron F. Reitz et al., Office of the Attorney General, P.O. Box 12548, Austin, Texas 78711-2548, (512)936-1700

DEFENDANTS

U.S. Department of Health and Human Services, et al.

County of Residence of First Listed Defendant
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

U.S. Department of Justice

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☒ 2 U.S. Government Defendant
- ☐ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*

(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

Click here for: Nature of Suit Code Descriptions.

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☐ 365 Personal Injury - Product Liability
- ☐ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 835 Patent - Abbreviated New Drug Application
- ☐ 840 Trademark
- ☐ 880 Defend Trade Secrets Act of 2016

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC 3729(a))
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit (15 USC 1681 or 1692)
- ☐ 485 Telephone Consumer Protection Act
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☒ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

- ☒ 1 Original Proceeding
- ☐ 2 Removed from State Court
- ☐ 3 Remanded from Appellate Court
- ☐ 4 Reinstated or Reopened
- ☐ 5 Transferred from Another District *(specify)*
- ☐ 6 Multidistrict Litigation - Transfer
- ☐ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing **(Do not cite jurisdictional statutes unless diversity)**:
5 U.S.C. 701 et seq.

Brief description of cause:
Administrative Procedure Act challenge to agency's failure to respond to petition for rulemaking

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.

DEMAND $

CHECK YES only if demanded in complaint:
JURY DEMAND: ☐ Yes ☒ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE DOCKET NUMBER

DATE 1/18/2022

SIGNATURE OF ATTORNEY OF RECORD /s Gene P. Hamilton

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I.(a) **Plaintiffs-Defendants.** Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) **County of Residence.** For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) **Attorneys.** Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. **Jurisdiction.** The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.
United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked**.** (See Section III below**; NOTE: federal question actions take precedence over diversity cases.**)

III. **Residence (citizenship) of Principal Parties.** This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. **Nature of Suit.** Place an "X" in the appropriate box. If there are multiple nature of suit codes associated with the case, pick the nature of suit code that is most applicable. Click here for: Nature of Suit Code Descriptions.

V. **Origin.** Place an "X" in one of the seven boxes.
Original Proceedings. (1) Cases which originate in the United States district courts.
Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441.
Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
Multidistrict Litigation – Transfer. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407.
Multidistrict Litigation – Direct File. (8) Check this box when a multidistrict case is filed in the same district as the Master MDL docket.
PLEASE NOTE THAT THERE IS NOT AN ORIGIN CODE 7. Origin Code 7 was used for historical records and is no longer relevant due to changes in statue.

VI. **Cause of Action.** Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service.

VII. **Requested in Complaint.** Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. **Related Cases.** This section of the JS 44 is used to reference related cases, if any. If a related case exists, whether pending or closed, insert the docket numbers and the corresponding judge names for such cases. A case is related to this filing if the case: 1) involves some or all of the same parties and is based on the same or similar claim; 2) involves the same property, transaction, or event; 3) involves substantially similar issues of law and fact; and/or 4) involves the same estate in a bankruptcy appeal.

Date and Attorney Signature. Date and sign the civil cover sheet.

UNITED STATES DEPARTMENT
OF HEALTH AND HUMAN SERVICES

In re 42 C.F.R. § 70.1

PETITION FOR RULEMAKING

1. As the attorneys general of Oklahoma, Alabama, Arizona, Arkansas, Florida, Georgia, Indiana, Louisiana, Mississippi, Missouri, Montana, Nebraska, South Carolina, Texas, and Utah, we respectfully petition the U.S. Department of Health and Human Services (HHS) to amend its definition of "public health emergency" in 42 C.F.R. § 70.1. *See* 5 U.S.C. § 553(e). The Rule exceeds the agency's authority and infringes on U.S. and State sovereignty by unlawfully delegating to the World Health Organization (WHO) the authority to invoke health emergency powers solely based on decisions of the WHO. In addition, information that the American public has learned about the WHO since HHS adopted the rule confirms that the WHO should not be trusted with these decisions even were the rule authorized by law. Accordingly, Petitioner States request the deletion of definitions (3), (4), and (5) of "public health emergency" in 42 C.F.R. § 70.1.

BACKGROUND

2. 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. 42 U.S.C. § 264(a).

3. When enforcing these rules, HHS may inspect, alter, or destroy animals or articles founds 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).

4. On January 19, 2017, one day before President 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 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 HHS 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

[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.

> 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.

5. In responding to public comments criticizing this approach as a breach of sovereignty, HHS argued that it would not actually use definitions (3), (4), and (5) of public health emergency. 82 Fed. Reg. 6890, 6905-06. HHS insisted that it "will continue to make its own independent decisions regarding" public health emergencies. *See id.* at 6906.

6. Contradicting HHS's responses, the plain text of the rules purports to confer authority on HHS to rely solely on the determination by the WHO, rather than making independent decisions. When responding to comments, HHS admitted 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 definitions.

INTERESTS OF THE PETITIONERS

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

8. The applicable statute for public health emergencies asserts that the exercise of Federal authority preempts conflicting State laws. 42 U.S.C. § 264(e). Petitioners seek to protect the

applicability of their health and safety laws against unlawful preemption by the actions of Federal officials.

9. The federal statute and regulations also permit the federal government to encroach on State property and detain State personnel in a public health emergency situation. Petitioners seek to protect their property and personnel against unlawful action by federal officials.

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

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

RATIONALE FOR THE REQUESTED AMENDMENT

I. HHS should amend its rules because the existing definition of public health emergency exceeds HHS's authority.

12. All federal agencies, including HHS, are forbidden from delegating their decisions to foreign nations or international organizations absent express provision by Congress. Here, there is no treaty or international agreement that calls for or requires delegation like this. Even if there were such a treaty, Congress would need to implement such a treaty. 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.

13. The President has authority "to make Treaties, provided two thirds of the Senators present concur." U.S. Const. art II, § 2, cl. 2. Any such properly entered treaty "shall be the supreme Law of the Land." U.S. Const. art VI, cl. 2. Because treaties require the approval of the Senate, the domestic effect of treaties is controlled by any terms or conditions the Senate attaches to its ratification and by the presence or absence of implementing legislation following ratification. *See Bond*

v. United States, 572 U.S. 844, 850-51 (2014); *see also id.* at 889-91 (Thomas, J. concurring in the judgment).

14. The President also has authority to enter executive agreements in some circumstances. *See United States v. Belmont*, 301 U.S. 324, 330-31 (1937). Executive agreements rely solely on the President's authority in foreign relations, and they generally lack any domestic effect without an act of Congress. *See, e.g.*, *United States v. Sum of $70,990,605*, 234 F. Supp. 3d 212, 234 (D.D.C. 2017) (citing L. Henkin, *Foreign Affairs and the U.S. Constitution* 219, 226–28 (2d ed. 1996)).

15. The WHO Constitution was never ratified as a treaty by two-thirds of the Senate. Instead, Congress passed a joint resolution authorizing the President to participate in the WHO. *See* Pub. L. No. 80-643, 62 Stat. 441 (June 14, 1948).[2] Accordingly, the WHO Constitution is not a binding treaty but is instead an executive agreement that only has such effect on domestic legislation as Congress has expressly prescribed.

16. Congress has forbidden domestic effects of the WHO Constitution. When authorizing participating in the WHO, Congress stated that it approved participation "with the understanding that nothing in the Constitution of the World Health Organization in any manner commits the United States to enact any specific legislative program regarding any matters referred to in said Constitution." 22 U.S.C. § 290d.

17. Congress could provide for some domestic effects of participation in the WHO. Congress has expansive authority "[t]o regulate Commerce with foreign Nations." U.S. Const. art 1, § 8.

18. Nevertheless, Congress has not used that authority in this context. The Public Health Service Act provides for regulation by the "Surgeon General, with the approval of the Secretary." 42

[2] https://uscode.house.gov/statviewer.htm?volume=62&page=44

U.S.C. § 264(a). Nothing in that statute contravenes Congress's general command against committing the United States to any particular course of action based on decisions of the WHO.

19. In fact, Congress has particularly warned against preempting state powers in this context. *See* 42 U.S.C. § 264(e). This law provides that nothing in the relevant statutes or regulations "may be construed as superseding any provision of State law (including regulations and including provisions established by political subdivisions of States)." *Id.* The sole exception allows for preemption in the case of conflict with the exercise of Federal authority. *Id.* A statute that prioritizes protection of state law, state regulations, and even local law and regulations is a statute that severely constrains HHS's authority to interfere with Petitioner States.

20. HHS otherwise lacks authority to promulgate rules beyond its governing statutes. *See Food & Drug Admin. v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 125 (2000). This power is no different for public health emergencies. Congress has appropriately recognized the role of the executive branch in responding to a crisis while passing statutes that define that role. Thus, the President's responsibility to "take Care that the Laws be faithfully executed," U.S. Const. art. II, § 1, cl. 2, includes managing a public health emergency within the boundaries defined by Congress. The President may exercise that authority through officers he appoints, *id.* art. II, § 2, cl. 2, such as the Surgeon General and the HHS Secretary. He may also rely on inferior offices who are directed and supervised by those superior officers. *See, e.g.*, *United States v. Arthrex, Inc.*, 141 S. Ct. 1970, 1976 (2021). No provision of the Constitution authorizes further delegating this power beyond executive officers and their staff, including delegations to any foreign power or agency.

21. 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 that decision, 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.

22. While delegation to any outside group (including the WHO) is unlawful, delegating decisions to an international organization causes particular harm to the sovereignty of both the United States and the Petitioners.

23. 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 Petitioner 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, but delegations outside the United States inappropriately seek to strip authority from the people entirely.

24. No federal power over international relations allows the federal government to delegate police powers to an international organization. The federal government must stay firmly within the limits of the commerce clause when seeking to limit the reach of State police powers. U.S. Const. art I, § 8. To be sure, the federal government also has authority over international relations. *See Bond v. United States*, 572 U.S. 844, 855 (2014). Under governing case law, the use of the treaty power can potentially override the allocation of sovereign authority to govern national and State territory. *See id.* at 854 (citing *Missouri v. Holland*, 252 US 416, 432 (1920)). Nevertheless, it is undisputed that the federal government's authority over international relations does not include the authority to delegate any element of the federal government's sovereign police power outside the context of a treaty.

25. By permitting the WHO to determine when a public health emergency exists, HHS is attempting to use its interstate commerce authority to transfer 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 police powers that were neither given to it or to the federal government by the States.

26. Definition (3) of "public health emergency," which refers 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 Petitioner 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 making reports is an extreme violation of both State and federal sovereignty.

27. 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.

28. Constraining the use of authority under 42 U.S.C. § 264(d) by requiring an executive order under 42 U.S.C. § 264(b) does not resolve the delegation concern. It may be true that declaring a public health emergency as defined in 42 CFR § 70.1 is not sufficient to quarantine individuals because an executive order is also necessary. Nevertheless, it is still necessary to the process of issuing quarantine orders and shifting determinations about any "specific statutory requirement" to an outside group is unlawful. *U.S. Telecom Ass'n*, 359 F.3d at 567; *accord, Louisiana Forestry Ass'n Inc. v. Sec'y U.S. Dept. Labor*, 745 F.3d 653, 671 (3d Cir. 2014); *Fund for Animals v. Kempthorne*, 538 F.3d 124, 132 (2d Cir. 2008).

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

II. HHS should amend its rules because WHO is not a trustworthy agency for public health information.

30. Regardless of whether the delegation to WHO was lawful at the outset, *see supra* Part I, HHS should also repeal the definitions of public health emergency that refer to the WHO because more recent events demonstrate that the WHO allows political influence to manipulate its health information. As a result, even if the WHO were a reliable source of health information in 2017, it should not be regarded as a reliable source today.

31. Since HHS adopted the definitions at issue in 2017, Petitioner States, HHS, and other sovereigns around the world have grappled with the difficulties of the COVID-19 pandemic. The WHO should have played an important role in sharing information with member nations during a

global pandemic, but instead, it demonstrated that it could not and would not share information in a timely and accurate manner.

32. In January 2020, the WHO surprised many observers by failing to declare COVID a public health emergency under international rules even though COVID met the legal criteria for such a declaration. *See,* Mara Pillinger, *The WHO Held off on Declaring the Wuhan Coronavirus a Global Health Emergency. Here's Why*, Washington Post (Jan. 26, 2020).[3] Instead of reporting public health information, the WHO chose to repeat Chinese propaganda regarding COVID. *See* Zeynep Tufekci, *The WHO Shouldn't Be a Plaything for Great Powers*, The Atlantic (April 16, 2020);[4] *see also* World Health Organization (WHO) Twitter, Jan. 14, 2020.[5]

33. While denying the existence of human-to-human transmission of COVID, the WHO had already received information from Taiwan suggesting that such transmission was occurring. *See* Louise Watt, *Taiwan Says It Tried to Warn the World About Coronavirus. Here's What It Really Knew and When*, Time (May 19, 2020).[6] Even setting aside the politics regarding Taiwan's status for official reports, the WHO should have been able to use unofficial reports. Its 2005 revisions to the IHR were intended to enhance the ability of the WHO to identify fast-developing health conditions beyond official reports. *See, e.g.*, David P. Fidler & Lawrence O. Gostin, *The New International Health Regulations: An Historic Development for International Law and Public Health*, 34 J.L. Med. & Ethics 85, 90 (2006); James Revill, et al., Tools for Compliance and Enforcement from beyond WMD Regimes 14 (UNIDIR 2021) (discussing the IHR revisions). Those revisions failed at their purpose when the WHO needed to review what it considered unofficial reports. The WHO Director-General has

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[3] www.washingtonpost.com/politics/2020/01/26/who-held-off-declaring-wuhan-coronavirus-global-health-emergency-heres-why/
[4] https://www.theatlantic.com/health/archive/2020/04/why-world-health-organization-failed/610063/
[5] https://twitter.com/WHO/status/1217043229427761152
[6] https://time.com/5826025/taiwan-who-trump-coronavirus-covid19/

defended failure to act on Taiwan's information on the basis that "[t]he first report came from Wuhan," without explaining why an official report from China foreclosed examining data beyond official reports. *See* Remarks by Dr. Tedros Adhanom Ghebreyesus, Director-General of the WHO, at COVID-19 Virtual Press Conference, World Health Org. (April 20, 2020).[7]

34. While the WHO's malfeasance with COVID involved *denying* the existence of a pandemic, the WHO is also unreliable in *declaring* a public health emergency because it is captured by Chinese political interests. Relating to COVID, "the WHO decided to stick disturbingly close to China's official positions, including its transparent cover-ups." Tufekci, *supra* ¶ 30.

35. The WHO's recent activity also contrasts sharply with its handling of the 2003 SARS outbreak in China, where the WHO counteracted cover-up attempts by China. *See* Michael Collins, *The WHO and China: Dereliction of Duty*, Council on Foreign Relations (Feb. 27, 2020).[8] It appears that Chinese money since 2003 has successfully manipulated the leadership of the WHO into prioritizing China's political goals over accurate health information. *See id.*

36. The WHO's failures in the early part of the COVID pandemic are not an isolated incident. The WHO's 2021 report on the COVID pandemic was so unreliable that "American health experts and more than 50 other international specialists published an open letter that described the shortcomings of the study and called for establishing a structure and process outside of WHO for conducting subsequent investigations." *Origins of the COVID-19 Pandemic*, Congressional Research Service (June 11, 2021).[9]

37. Considering the WHO's politically captured status and its inability to produce reliable information because of its subordination to China, it should not be trusted when finding or denying

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[7] https://www.who.int/docs/default-source/coronaviruse/transcripts/who-audio-emergencies-coronavirus-press-conference-20apr2020.pdf
[8] https://www.cfr.org/blog/who-and-china-dereliction-duty
[9] https://crsreports.congress.gov/product/pdf/if/if11822

public health emergencies. It will be no less motivated by politics when finding those emergencies than when denying them. Accordingly, whatever merit reliance on the WHO held in 2017, HHS's definition of a public health emergency should not defer to WHO determinations now.

III. HHS should amend its rules because it has already conceded it does not intend to use these unlawful rules.

38. Regardless of whether HHS agrees or disagrees with Parts I-II of this Petition, it should repeal the definitions identified as problematic in this Petition because it has previously admitted it does not intend to use those regulations. In the Federal Register notice issuing the definition of public health emergency, HHS indicated that it would make independent decisions regarding public health emergencies. 82 Fed. Reg. 6890, 6906. Those independent decisions would continue to be cognizable under definitions (1) and (2) were this Petition granted. Accordingly, HHS would suffer no harm from granting the petition.

39. The only potential reason to retain unlawful rules that HHS does not believe it needs is to permit a future HHS to change its mind in later years. Under definitions (1) and (2), HHS would be constrained to rely on its independent judgment regardless of whether any future Secretary wanted to defer decisions to the WHO during a crisis. 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.

40. HHS's decision to include definitions of public health emergency that serve no foreseeable purpose was an arbitrary and capricious decision because there is no explanation or rationale for those definitions. Because, if we believe its protestations in the Federal Register, the existing HHS does not believe it needs definitions (3), (4), and (5) to manage public health emergencies, it should repeal them as unnecessary even if it does not want to address the legality issues and WHO concerns raised in Parts I-II of this Petition.

Request for Action

41. The Petitioner States request that HHS amend 42 C.F.R. § 70.1 by deleting definitions (3), (4), and (5) of public health emergency in that rule.

Dated July 18, 2022

Respectfully Submitted,

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DEPARTMENT OF HEALTH & HUMAN SERVICES

The Honorable John O'Connor
Attorney General
313 N.E. 21st Street
Oklahoma City, Oklahoma 73105

Dear Attorney General O'Connor:

I am responding on behalf of Health and Human Services (HHS) Secretary Xavier Becerra to your petition submitted on behalf of the Attorney Generals of 15 U.S. States[1] (hereinafter, "the petitioners") to amend the definition of "public health emergency" in 42 CFR 70.1. Under the Administrative Procedure Act, each agency must "give an interested person the right to petition for the issuance, amendment, or repeal of a rule." 5 U.S.C. § 553(e).

Your petition raises the following concerns:

- Definitions 3, 4, and 5 of "public health emergency" as used in 42 CFR 70.1 exceeds the HHS and the Centers for Disease Control and Prevention (CDC) statutory authority because it constitutes an unlawful delegation of authority to either the World Health Organization (WHO) (in the case of definitions 4 and 5) or to a foreign nation's decision to report a disease event to WHO (in the case of definition 3).
- HHS should repeal definitions in 42 CFR 70.1 that reference WHO because WHO ostensibly allows political influence from China to manipulate its health decisions.
- HHS/CDC would not be harmed by repealing definitions 3, 4, and 5 because it previously stated as part of its 2017 final rulemaking that it would exercise its independent judgment in assessing whether a public health emergency existed under 42 CFR part 70.

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." 42 U.S.C. § 264(a). Section 361(b) provides that regulations authorizing the apprehension, detention, or conditional release of individuals shall be specified in Executive orders of the President[2] upon

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[1] These States are Oklahoma, Alabama, Arizona, Arkansas, Florida, Georgia, Indiana, Louisiana, Mississippi, Missouri, Montana, Nebraska, South Carolina, Texas, and Utah.

[2] The current list of "quarantinable" communicable diseases includes Cholera, Diphtheria, infectious Tuberculosis, Measles, Plague, Smallpox, Yellow Fever, Viral Hemorrhagic Fevers, Severe acute respiratory syndromes, and Flu that can cause a pandemic. Executive Order 13295 (April 4, 2003), as modified by Executive Orders 13375 (April 1, 2005), 13674 (July 31, 2014), and 14047 (Sept. 17, 2021). Coronavirus disease 2019 is subject to federal quarantine and isolation because it meets the definition for Severe acute respiratory syndromes.

the recommendation of the Secretary, in consultation with the Surgeon General.[3] 42 U.S.C. § 264(b). Section 361(c) provides that regulations authorizing apprehension, detention, examination, or conditional release of individuals shall be applicable only to individuals coming into a State or possession from a foreign country or a possession. 42 U.S.C. § 264(c).

Section 361(d)(1) authorizes the apprehension and examination of individuals who are in the "qualifying stage" of a communicable disease if such individuals are (A) "moving or about to move from a State to another State;" or (B) "a probable source of infection to individuals who, while infected with such disease in a qualifying stage, will be moving from a State to another State." 42 U.S.C. § 264(d)(1). A "qualifying stage" is further defined in section 361(d)(2) as "a communicable stage;" or "a precommunicable stage if the disease would be likely to cause a public health emergency if transmitted to other individuals." 42 U.S.C. § 264(d)(2).

On August 15, 2016, HHS published a Notice of Proposed Rulemaking (81 FR 53240) in which we proposed a new definition of "public health emergency." HHS/CDC felt it was important to define ''public health emergency'' as used under section 361(d)(2) to provide the public with a clear understanding of HHS/CDC's authority for interstate quarantine, isolation, or conditional release. We requested public comment on this definition.

As defined under 42 CFR 70.1, HHS proposed that "public health emergency" mean:

> (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; or
> (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)); or
> (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.

In the Final Rule published on January 19, 2017, HHS discussed the public comments received on this proposed definition (82 FR 6905-6910). HHS explained that "public health emergency" as used in § 361(d) differed from how the term is used in other provisions of the Public Health Service Act because it authorizes specific public health measures (apprehension and

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[3] Although statute originally assigned authority to the Surgeon General, these statutory powers and functions were later transferred to the Secretary of Health, Education, and Welfare, now the Department of Health and Human Services Secretary. *See* Reorganization Plan No. 3 of 1966, 31 Fed. Reg. 8855 (June 25, 1966), reprinted in 80 Stat. 1610 (1966); *see also* 20 U.S.C. § 3508(b).

examination) to specific individuals (those in the precommunicable stage of a quarantinable communicable disease), but only if the disease would be likely to cause a public health emergency (82 Fed. Reg. 6905 Jan. 19, 2017). HHS/CDC therefore considered it essential to define the term 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.

We note that the term "public health emergency" is only referenced in the definitions section of 42 CFR part 70, as its own definition and under the definition of "qualifying stage" which quotes from § 361(d) verbatim. Apprehension and detention of individuals with quarantinable communicable diseases is then authorized under 42 CFR 70.6 if the CDC Director reasonably believes the individual to be in the "qualifying stage" of the disease. Any exercise of authority under § 70.6 is further governed by other substantive provisions under part 70, including § 70.14 setting forth additional requirements relating to the issuance of federal quarantine orders. Among other things, such orders must identify the individuals or groups to be quarantined, the location of the quarantine, explain the factual basis for the Director's reasonable belief that the individual is in the qualifying stage of the disease, explain the factual basis for the Director's reasonable belief that the individual is moving or about to move from one U.S. State into another or otherwise constitutes a probable source of infection to other individuals moving between U.S. States, explain that the order will be reassessed within 72 hours, and notify the individual of the opportunity for an agency medical review, as well as the potential for criminal penalties if non-compliant.

In the 2017 Final Rule, HHS also addressed comments that incorporating references to WHO in the definition of public health emergency implicated U.S. sovereignty and rejected these concerns. Specifically, HHS found:

> By including references to a [Public Health Emergency of International Concern (PHEIC)], HHS/CDC is not constraining its actions or makings [sic] its actions subject to the dictates of the WHO. Rather, the declaration or notification of a PHEIC is only one 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. While HHS/CDC will give consideration to the WHO's declaration of a PHEIC or the circumstances under which a PHEIC may be notified to the WHO, HHS/CDC will continue to make its own independent decisions regarding when a quarantinable communicable disease may be likely to cause a public health emergency if transmitted to other individuals. Thus, HHS/CDC disagrees that referencing the WHO determination of a PHEIC results in any relinquishment of U.S. sovereignty.[4]

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. Between January and March 2020, HHS/CDC, in conjunction with other federal agencies, repatriated approximately 1,100 individuals from Wuhan, China, and the *Diamond Princess* cruise ship in Yokohama, Japan, in response to the coronavirus disease 2019 (COVID-19) pandemic. HHS/CDC quarantined these individuals for 14 days at five U.S.

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[4] 82 FR 6905-6906

Department of Defense (DOD) facilities. HHS/CDC, in conjunction with other federal agencies, later quarantined approximately 2,000 individuals from the *Grand Princess* cruise ship in San Francisco, California. These individuals were similarly quarantined at a variety of DOD and other facilities for the incubation period of the disease until CDC determined that such practices were no longer warranted based on the evolution of the pandemic.

Although HHS/CDC, in the case of the Wuhan and *Diamond Princess* evacuees relied on complementary quarantine authorities at 42 CFR 71.32(a), 71.33, pertaining to foreign arrivals, the agency also referenced 42 CFR 70.6. Specifically, CDC found that these individuals met the standards for quarantine under 42 CFR 70.6 because they were reasonably believed to be in a qualifying stage of the disease and, if released from quarantine, would be moving or are about to move from one U.S. State into another or constitute a probable source of infection to others who may be moving from one U.S. State into another.

In the case of the *Grand Princess*, HHS/CDC relied solely on 42 CFR 70.6 because these individuals were already in the United States and not in the process of arriving from a foreign country when placed under quarantine. Both 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. The quarantine orders also referenced the Secretary's determination that COVID-19 constituted a public health emergency under the Public Health Service Act. Additionally, these quarantine orders (consistent with agency practice) were supported by medical declarations signed under penalty of perjury setting forth additional pertinent facts and circumstances as to what was known about COVID-19 at the time and the agency's determination as to the necessity for apprehension and detention.

In conclusion, the petition does not raise any significant concerns that were not previously raised and considered by HHS/CDC when finalizing the proposed regulations in 2017. The language and structure of the regulations, as well as agency practice in implementation, furthermore, belie the contention that an unlawful delegation has occurred because apprehension and quarantine determinations are only carried out subject to the CDC Director's independent judgment.

Although we acknowledge the concerns noted in the petition regarding purported political influence on WHO decision-making, they do not support removing references to that organization in 42 CFR 70.1. Rather, HHS/CDC considers it 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 when determining whether a public health emergency exists using its own independent judgment. Furthermore, we 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.

These efforts include strengthening the IHR (2005). We believe in the need for strong global relationships to combat COVID-19 and prepare for future pandemics. Since the 2005 revision of the IHR, the world has benefited from an increased level of transparency, improved rapid pathogen information sharing and stronger response coordination. However, the COVID-19 pandemic and other recent public health emergencies have revealed gaps and shortcomings. The U.S. is seeking targeted amendments to increase rapid and timely sharing of data and information

related to outbreaks and pathogens between countries and to enhance early warning triggers so that countries can take actions to prepare for and respond to emergencies such as COVID-19.

The IHR's origins date back to 1851, when international efforts sought to address the spread of infectious diseases entering Europe from Asia; this was codified in the 1892 International Sanitary Convention (ISC), which sought to protect countries from infectious disease threats. When the WHO was created in 1948, oversight of the ISC became part of its mandate. In 1951, the World Health Assembly (WHA) replaced the ISC with the International Sanitary Regulations, which covered six diseases; in 1969, these were further revised and renamed as the International Health Regulations (IHR). With the increase in international travel and trade, and the emergence, re-emergence and international spread of emerging infectious diseases, in 1995, WHO Member States recognized a need for a substantial revision to extend the scope of diseases and related health events covered by the IHR to take into account almost all public health risks (biological, chemical, radiological, or nuclear in origin) that might affect human health, irrespective of the source. The revised IHR (2005) entered into force in 2007, have 196 States Parties, and require States Parties to notify a wide range of events to the WHO.

The IHR (2005) constitutes a legally binding global health security framework to prevent, detect, and respond to acute public health risks that have the potential to cross borders and threaten the health of populations worldwide, while minimizing interference with world travel and trade. However, the IHR has not been fully implemented by States Parties, and COVID-19 stressed health systems, further exposing existing gaps and weaknesses. Criticisms from numerous reviews over the last 15 years include: a lack of country core capacities in pandemic preparedness, insufficient implementation of requirements by national governments, weaknesses in WHO´s emergency response systems and programs, and other gaps and challenges in pandemic preparedness and response at national and international levels, including fundamental weaknesses in health systems and lack of indicators to detect and respond to new infectious disease threats (e.g., unknown viruses). Although there have been numerous proposals to improve the IHR (2005) through amendment, none have been taken up yet.

At this year's WHA, the United States proposed targeted IHR amendments that were developed and refined over the last year in consultation with fellow WHO Member States. Strengthening the global health infrastructure as quickly and effectively as possible is critically important as we begin the third year in our battle against COVID-19. The United States discussed these proposed amendments with other WHO Member States as part of the Working Group on Strengthening WHO Preparedness and Response, whose report was considered by the Health Assembly during this year's meeting.

In resolution WHA75.12 of May 28, 2022, the Seventy-fifth World Health Assembly adopted amendments to Articles 55, 59, 61, 62 and 63 of the IHR, as proposed by the United States. These amendments strengthen requirements for reporting emergencies to the WHO. These and other amendments the United States is proposing, however, do not provide the WHO with enforcement powers and do not authorize WHO to interfere in the United States' internal decision-making processes. Strengthening the existing IHR does not diminish U.S. sovereignty or the ability of Americans to make their own healthcare decisions and claims in that regard are false. The effort to strengthen the IHR is about improving transparency and speeding action, so

nations have the information and the recommendations they can use. Finally, strengthening the IHR also helps to ensure that other countries do their part on global health, something we should all embrace.

Lastly, your assertion that HHS/CDC would not be harmed by deleting definitions 3, 4, and 5 of "public health emergency" as used in 42 CFR 70.1, even if accurate, does not justify the expenditure of agency resources to amend the regulations. Also, as explained in the 2017 Final Rule, HHS/CDC considered it 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 when making such a determination using its own independent judgment. Accordingly, we decline the petitioners' request to amend 42 CFR 70.1 by deleting definitions 3, 4, and 5 of "public health emergency" at this time.

Sincerely,

Marvin Figueroa
Director, Intergovernmental and External Affairs