## 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;<sup>1</sup> 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

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<sup>&</sup>lt;sup>1</sup> 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).<sup>2</sup> 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

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<sup>&</sup>lt;sup>2</sup> 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.
- 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). 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); see also World Health Organization (WHO) Twitter, Jan. 14, 2020.
- 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).<sup>6</sup> 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

www.washingtonpost.com/politics/2020/01/26/who-held-off-declaring-wuhan-coronavirus-global-health-emergency-heres-why/

https://www.theatlantic.com/health/archive/2020/04/why-world-health-organization-failed/610063/

<sup>&</sup>lt;sup>5</sup> https://twitter.com/WHO/status/1217043229427761152

<sup>&</sup>lt;sup>6</sup> 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).<sup>7</sup>

- 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). 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).
- 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

https://www.who.int/docs/default-source/coronaviruse/transcripts/who-audio-emergencies-coronavirus-press-conference-20apr2020.pdf

<sup>&</sup>lt;sup>8</sup> https://www.cfr.org/blog/who-and-china-dereliction-duty

<sup>9</sup> 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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