

# Executive Authority Under the U.S. Constitution to Enter a Pandemic Treaty or Other International Agreement

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## I. Introduction

The devastating effects of the COVID-19 pandemic can be told in numbers. As of this writing, more than 4.5 million people worldwide have died, 219 million have been infected and many face weeks, months or years of “long covid” recovery.<sup>1</sup> For children, long-covid occurs at 10-13% of cases, imposing potentially life-long disability.<sup>2</sup> Economically, the productivity, job loss, and response costs exceed \$16 trillion in the U.S. alone.<sup>3</sup> The IMF estimates that, through October 2020, the global cost stood at \$28 trillion.<sup>4</sup> Supply chain disruptions now vex every country in the world.

The numbers reflect a world that was poorly prepared when the new pathogen emerged, struggled to coordinate its response after the threat became clear, and, as a result, full recovery may be delayed by a decade or more.<sup>5</sup> While vaccination rates have climbed to herd immunity thresholds in the wealthiest countries, 95% of the world’s population in low-income countries does not have access to a first dose.<sup>6</sup> The World Health Organization was disempowered from leading the global response and possessed few instruments to do so under the only existing international disease control agreement, the International Health Regulations (2005), adopted after the global experience with SARS-CoV-1 in 2002-03.<sup>7</sup>

On March 21, 2021, the leaders of 26 countries, the World Health Organization and the President of the European Council called for the World Health Assembly to consider the adoption of a pandemic treaty given the glaring gaps in the national and global responses to the COVID-19 pandemic.<sup>8</sup> The 74th session of the World Health Assembly in May 2021 took the extraordinary measure of calling a Special Session, scheduled for November 29-December 1, 2021, to consider precisely such a legal instrument.<sup>9</sup> The United States has

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<sup>1</sup> Daniel Shork, *The World COVID Death Total Tops 4 million*, N.Y. TIMES, Aug. 7, 2021 available at <https://www.nytimes.com/2021/07/08/world/covid-death-toll-four-million.html>

<sup>2</sup> Dyani Lewis, *Long Covid and Kids: Scientists Race to Find Answers*, NATURE, July 14, 2021 available at <https://www.nature.com/articles/d41586-021-01935-7>

<sup>3</sup> David Cutler and Lawrence Summers, *The COVID-19 Pandemic and the \$16 trillion Virus*, JAMA available at <https://jamanetwork.com/journals/jama/fullarticle/2771764>.

<sup>4</sup> *IMF estimates global Covid cost at \$28tn in lost output*. THE GUARDIAN, available at <https://www.theguardian.com/business/2020/oct/13/imf-covid-cost-world-economic-outlook>

<sup>5</sup> OECD, *Coronavirus (COVID-19) Vaccines for Developing Countries: An Equal Shot at Recovery*. Feb. 4, 2021 available at <https://www.oecd.org/coronavirus/policy-responses/coronavirus-covid-19-vaccines-for-developing-countries-an-equal-shot-at-recovery-6b0771e6/>

<sup>6</sup> Kaiser Family Foundation, *Tracking Global Vaccine Equity*, available at <https://www.kff.org/coronavirus-covid-19/issue-brief/tracking-global-covid-19-vaccine-equity/>

<sup>7</sup> Stephen Green and Lorenzo CLadi, *COVID-19: Trump halts WHO Funding in Move Labeled Petulant and Short-Sighted*, 369 BMJ Apr. 27, 2020 available at <https://www.bmj.com/content/369/bmj.m1502/rr-1>

<sup>8</sup> Lawrence Gostin, Sam Halabi, and Kevin Klock, *An International Agreement on Pandemic Prevention and Response*, JAMA, Sept. 15, 2021 available at <https://jamanetwork.com/journals/jama/fullarticle/2784418>

<sup>9</sup> World Health Assembly, *Special Session to Consider a WHO convention, agreement, or other international instrument on pandemic preparedness and response*, May 25, 2021 available at [https://apps.who.int/gb/ebwha/pdf\\_files/WHA74/A74\\_ACONF7-en.pdf](https://apps.who.int/gb/ebwha/pdf_files/WHA74/A74_ACONF7-en.pdf).

remained circumspect with regard to a formal treaty, publicly articulating support for revision of the International Health Regulations (2005) and some improvements to governance at the World Health Organization, while remaining open to the development of a new international agreement.<sup>10</sup>

The reasons for this circumspection are manifold. First, the U.S. may simply have determined that a comprehensive and binding treaty is not in its interest. The issue of vaccine access has featured prominently in the global conversation leading to the declaration that a pandemic agreement may be necessary.<sup>11</sup> Any visibility as to vaccine access and equity would cast the U.S. in a poor light to say nothing of the substantive provisions of a treaty addressing vaccine access, which may affect companies based in the U.S. and which may object to measures that may affect their profitability and flexibility. Over the course of the pandemic, companies based in the U.S. developed three of the four most successful vaccines and, in its contracts for their procurement, the U.S. government prohibited the possibility that doses might be shipped elsewhere, even to those countries that may be in desperate need.<sup>12</sup> Second, the U.S. may in fact favor the establishment of a new treaty, but insist on certain reforms at the WHO governance level before entrusting it with new and perhaps powerful authority to prevent, prepare for, and respond to, future pandemics.<sup>13</sup> Third, the U.S. may be staking out a preliminary position of neutrality, so that even its willingness to join may secure benefits from its participation in negotiation. It has been a long-held tactic of the United States to participate in treaty negotiations, even if it ultimately never joins the treaty it helped draft.<sup>14</sup> The U.N. Convention on the Law of the Sea is an archetypal case of such behavior.<sup>15</sup>

Just as relevant is how the U.S. negotiating position will be shaped by its domestic constitutional framework. The U.S. Constitution charges the President with responsibility for serving as the voice of the country in international affairs, but also gives authority to Congress and, much less so, the U.S. Supreme Court and the judiciary in shaping what the President may and may not do.<sup>16</sup> Article I vests Congress with authority over most matters that require the raising and expenditures of revenues, the regulation of the armed forces, defining the content and relevance of international law, and the regulation of foreign commerce.<sup>17</sup>

Article II vests authority with the President to negotiate treaties, although two-thirds of the Senate must concur with the treaty text in order to become law. Separately, Article II authorizes the Executive to “receive Ambassadors” generally interpreted to mean that the President is entrusted to have the authority to recognize foreign governments and to therefore govern related matters pertinent to the conduct of diplomacy.<sup>18</sup> The President is also the Commander-in-Chief, giving him independent authority with respect to national security affairs.<sup>19</sup>

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<sup>10</sup> Anthony Blinken and Xavier Becerra, *Making the World Safer from Future Pandemics*, JAMA, Aug. 31, 2021 available at <https://jamanetwork.com/journals/jama/fullarticle/2783866>.

<sup>11</sup> World Health Assembly, *supra* note 9.

<sup>12</sup> Katherine Eban, *We are Hoarding: Why the U.S. Still Can't Donate Vaccines to Countries in Need*, VANITY FAIR, Aug. 6, 2021 available at <https://www.vanityfair.com/news/2021/04/why-the-us-still-cant-donate-covid-19-vaccines-to-countries-in-need>

<sup>13</sup> United States of America Proposal on Targeted Amendments to the International Health Regulations (IHR), policy position on file with author.

<sup>14</sup> Antonia Chayes, *How American Treaty Behavior Threatens National Security*, 33 INTERNATIONAL SECURITY 45-81 (2008).

<sup>15</sup> *Id.* See also U.S. Signature to the Rome Statute Establishing the International Criminal Court, which noted that the U.S. was signing with the intention to further influence the drafting of the final text.

<sup>16</sup> *United States v. Curtiss-Wright Export Corp.*, 299 U.S. 304 (1936); *Youngstown Sheet and Tube v. Youngstown Sheet & Tube Co. v. Sawyer*, 343 U.S. 579 (1952) (Jackson, J. concurring).

<sup>17</sup> U.S. Constitution, Art. I, § 8, cl. 10.

<sup>18</sup> U.S. Constitution, Art. II, § 2.

<sup>19</sup> *Id.*

With respect to the judiciary, Article III dedicates to the U.S. Supreme Court original jurisdiction over certain matters affecting foreign relations, but it largely plays a peripheral role in the formation and execution of foreign policy and has adopted a number of judiciousness and interpretation doctrines to avoid interference with the so-called “political questions” about foreign policy dedicated to Congress and the President.<sup>20</sup> For example, the U.S. Supreme Court has determined that it is not competent to determine whether the U.S. Senate must concur with a President’s decision to exit a treaty, even though it is constitutionally clear they must do so in order to join the same treaty.<sup>21</sup>

Despite the availability of a specific constitutional mechanism to govern treaty relations, the presidentially-negotiated, Senate-confirmed treaty has fallen into desuetude. Since the administration of Franklin Roosevelt, only 6% of international agreements have been concluded through the Senate ratification process.<sup>22</sup> Senate concurrence was last used for the New START treaty with Russia in 2011, although other agreements have been adopted through both chambers of Congress with more than two-thirds of Senators in support.<sup>23</sup> It is clear from the composition and statements from current U.S. Senators that a pandemic treaty has no chance of achieving two-thirds concurrence of the chamber as it is now comprised.<sup>24</sup>

Outside the treaty process, the President may nevertheless conclude agreements including so-called congressional-legislative agreements accomplished with varying levels of assent by Congress and sole executive agreements, concluded within the scope of the President’s Article II authority. These kinds of agreements have been used since the Founding, and are the most likely routes to U.S. participation in an international pandemic agreement.

The U.S. has faced this situation before. It joined the Paris Climate Accords through negotiation by the President (through the Secretary of State) carefully crafting its legal position to fall within domestic authorities. The President enjoyed his widest authority for provisions governed by the U.N. Framework on Climate Change (which the Senate ratified in 1992) and the Clean Air Act (which Congress had adopted by large majorities in 1970).<sup>25</sup> The President’s position was similarly strong with respect to provisions that affected information-sharing, which has been interpreted as authorized by Article II since the adoption of the U.S. Constitution.

Thus, the content and process of pandemic treaty negotiations will be shaped by current international agreements, including the International Health Regulations (2005), which the U.S. joined as a sole executive agreement through its accession to WHO authority. The purpose of this Essay is to identify how the U.S. may join an international pandemic agreement, especially when both Congressional chambers are so evenly divided, and one party has so clearly expressed its pessimism about international agreements in general, and a

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<sup>20</sup> Louis HENKIN, *FOREIGN AFFAIRS AND THE CONSTITUTION* 26-27 (1972); *Atlee v. Richardson*, 411 U.S. 911 (1973), *aff’d* *Atlee v. Laird*, 347 F. Supp. 689 (E.D. Pa. 1972).

<sup>21</sup> *Goldwater v. Carter*, 444 U.S. 996 (1979). While the Court considered the case non-justiciable under the posture presented to it, Justice Powell suggested that a valid Senate resolution contesting the President’s action may be justiciable. Under current law, there is no official ruling on whether the President has the power to break a treaty without the approval of Congress, but, relatedly, it is likely that any subsequent Court would find the matter dedicated to the political branches.

<sup>22</sup> Congressional Research Service, *Treaties and Other International Agreements: the Role of the U.S. Senate* (2001).

<sup>23</sup> U.S. Korea Free Trade Agreement, available at <https://ustr.gov/trade-agreements/free-trade-agreements/korus-fta>.

<sup>24</sup> Elaine Ruth Fletcher, *U.S. Holds Back on Move Toward Pandemic Treaty*, HEALTH POLICY WATCH, May 21, 2021 available at <https://healthpolicy-watch.news/exclusive-us-still-holding-back-on-bold-move-toward-pandemic-treaty/>.

<sup>25</sup> 42 U.S.C. 7401 et seq.

pandemic treaty in particular, leaving the most likely constitutional pathways running through Presidential action based in existing statutory authorizations or sole Presidential authority under the U.S. Constitution.<sup>26</sup>

## II. The U.S. Constitutional Framework

### A. Treaties

The U.S. Constitution authorizes the President to “make Treaties” provided that “two thirds of the Senators present concur.”<sup>27</sup> Once properly adopted, treaties become binding federal law, just as statutes adopted through bicameral deliberation and signature by the President.<sup>28</sup> While the importance of treaties as federal law is made clear in the constitutional text, especially the Supremacy Clause, the Founders never envisioned them as the exclusive means by which the United States would enter into international agreements. More importantly, the effect of treaties is legally divided between their internal effect, where they may impart individually enforceable rights, and their external effect, where they influence the relationship of the U.S. to international partners including both foreign governments and international organizations.<sup>29</sup>

Because the Founders never intended for the Presidential-Senatorial treaty-making process to serve as the only channel for formalizing international commitments that could bind the U.S. internationally, they also addressed different forms of international agreement, particularly in Article I.<sup>30</sup> The treaty process was intentionally arduous given its ability to adopt federal law without the House of Representatives (indeed, the ability of the treaty process to do what the bicameralism process could not remains controversial).<sup>31</sup> In the current political climate, it is extremely unlikely that an international pandemic agreement could be made with the consent of the Senate. However, agreements made with the consent of the Senate are historically rare. Nearly 90 percent of international agreements (approximately 15,000 agreements) that the U.S. has entered since World War II have been approved outside the constitutional treaty process.<sup>32</sup>

### B. Congressional-Executive Agreements

In addition to treaties, Article I, Section 10 of the U.S. Constitution speaks of “agreements”, “compacts”, “confederations”, and “alliances”, all of which the U.S. used from its earliest years as a constitutional republic.

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<sup>26</sup> 22 U.S.C. Section 290e (“The Congress of the United States, recognizing that the diseases of mankind, because of their widespread prevalence, debilitating effects, and heavy toll in human life, constitute a major deterrent to the efforts of many peoples to develop their economic resources and productive capacities, and to improve their living conditions, declares it to be the policy of the United States to continue and strengthen mutual efforts among the nations for research against diseases such as heart disease and cancer. In furtherance of this policy, the Congress invites the World Health Organization to initiate studies looking toward the strengthening of research and related programs against these and other diseases common to mankind or unique to individual regions of the globe.”).

<sup>27</sup> U.S. Constitution, Art. II, § 2.

<sup>28</sup> U.S. Constitution Art. VI.

<sup>29</sup> *Asakura v. City of Seattle*, 265 U.S. 332, 342- 43 (1924).

<sup>30</sup> Suzanna Sherry, *The Founders’ Unwritten Constitution*, 54 U. CHI. L. REV. 1127, 1137 (1987).

<sup>31</sup> In *Missouri v. Holland*, the U.S. Supreme Court validated the use of the treaty process to regulate state authority over migratory birds which had been determined to be impermissible as an overreach of federal authority when adopted pursuant to statute. That decision was left undisturbed by *Bond vs. United States*, although in that decision the Supreme Court concluded that there must be a clear statement from Congress if the intent is to disturb the otherwise settled boundary between state and federal authority.

<sup>32</sup> Nigel Purvis, *The Case for Climate Protection Authority*, 49 VA. J. INT’L L. 1007, 1018 (2009).

“During the first half-century of its independence, the United States was party to sixty treaties and to twenty-seven published executive agreements” concluded outside the treaty process.<sup>33</sup>

These other forms of concluding international agreements fall into two general categories: congressional-executive (or legislative-executive) agreements and sole executive agreements, created under the President’s own constitutional authority to “take care” that the United States’ laws be faithfully enforced<sup>34</sup> and pursuant to responsibilities collectively understood as the President’s foreign affairs power.<sup>35</sup> Constitutionally, the President may enter into an executive agreement, which may be defined as a “treaty” under international law, even if it could not be used to justify enforceable rights vis-à-vis states or individuals within U.S. territory or as understood within the meaning of Article VI’s Supremacy Clause.<sup>36</sup>

## 1. Current Statutory Authority

The United States Congress has adopted a number of statutory provisions that authorize the President to undertake broad coordinating action to advance global health. When Congress authorized the U.S. to join the World Health Organization, it declared that “[t]he Congress of the United States, recognizing that the diseases of mankind, because of their widespread prevalence, debilitating effects, and heavy toll in human life, constitute a major deterrent to the efforts of many peoples to develop their economic resources and productive capacities, and to improve their living conditions, declares it to be the policy of the United States to continue and strengthen mutual efforts among the nations for research against [such] diseases . . .”<sup>37</sup>

The United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003 directed the President to “establish a roadmap to link investments in specific disease programs to the broader goals of strengthening health systems and infrastructure and to integrate and coordinate HIV/AIDS, tuberculosis, or malaria programs with other health or development programs, as appropriate” all of which may be used to justify specific commitments under a pandemic treaty.

Similarly, the Pandemic and All-Hazards Preparedness Act of 2006 and the Pandemic and All-Hazards and Advancing Innovation Act of 2019 provided broadly worded Congressional authorizations for the U.S. to engage and support international organizations and partners with respect to national security threats posed by infectious and anti-microbial resistant diseases.<sup>38</sup> Current statutory authorizations provide one source the President, Secretary of State, and Secretary of Health and Human Services may consult when deliberating as to the content of an international pandemic agreement.

This is almost precisely how President Obama joined the Paris Climate Accords in in 2016 (and how President Biden anchored rejoining in 2021). Obama justified joining the Paris Agreement through his plenary authority over foreign affairs, the federal statutory framework for the protection of the environment, especially the Clean Air Act, and existing treaties, most importantly the 1992 Framework Convention on Climate Change to which the U.S. Senate gave its advice and consent in 1992.

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<sup>33</sup> Peter L. Fitzgerald, *Executive Agreements and the Intent behind the Treaty Power*, 2 HASTINGS CONST. L.Q. 757 (1975) available at: [https://repository.uchastings.edu/hastings\\_constitutional\\_law\\_quaterly/vol2/iss3/4](https://repository.uchastings.edu/hastings_constitutional_law_quaterly/vol2/iss3/4).

<sup>34</sup> U.S. Constitution, Art II, § 3

<sup>35</sup> See U.S. Constitution, Art. II, §§ 1, 2, 3; United States 11 Foreign Affairs Manual § 723.2- 2(C).

<sup>36</sup> “[T]he distinction between so-called ‘executive agreements’ and ‘treaties’ is purely a constitutional one and has no international significance.” Harvard Research in International Law, *Draft Convention on the Law of Treaties*, 29 AMER. J. INT. L. 697 (Supp.) (1935).

<sup>37</sup> 22 U.S.C. § 290e.

<sup>38</sup> Pandemic and All-Hazards Preparedness Act (PAHPA), [Public Law No. 109-417](#); Pandemic and All-Hazards Preparedness and Advancing Innovation Act (PAHPAIA), [Public Law No. 116-22](#).

In negotiating the Paris Agreement, the Executive Branch took great pains to remain within the confines of its authority as provided by (1) the President’s plenary powers; (2) federal statutes, particularly the Clean Air Act; and (3) existing treaties, most notably the 1992 Framework Convention on Climate Change, to which the Senate gave its advice and consent in 1992, under the George H.W. Bush Administration, which subsequently ratified the Convention for the United States. Even the most cursory review of the text of the Paris Agreement discloses a careful, purposeful alternation between the mandatory “shall”—indicating a binding obligation governed by international law—and the hortatory “should”—non-binding statements of strictly political intent without legal force. Indeed, the U.S. delegation held up the closing minutes of the conference that adopted the Paris Agreement over the should/shall distinction in an important provision of the Agreement addressing the need for developed country parties to undertake increasingly ambitious emissions reductions goals over time. A close read of the Paris Agreement demonstrates that the U.S. delegation was entirely successful in navigating the line delineating the President’s legitimate exercise of his existing authority. If anything, the American negotiators were excessively conservative, in insisting on hortatory language when legally binding obligations were arguably entirely appropriate.<sup>39</sup>

## 2. Advanced Congressional Authorization

While current statutory authority provides one body of law through which the President may shape pandemic treaty provisions, an alternative source is to obtain advance authorization from Congress, by simple majorities, for broad authority leading to the pandemic negotiations. This is how trade agreements have been concluded for over a century.<sup>40</sup> From 1890, Congress authorized the President to bargain over reciprocity in tariff reductions with foreign governments with no requirement of subsequent legislative implementation. In 1934, Congress authorized the President to not only bargain freely over tariff reductions, but to address other barriers to international trade and accomplish reductions through proclamation.<sup>41</sup>

Congress could also adopt so-called fast-track authority used for more current international trade agreements. Fast-track authority is the delegation of authority by Congress ex ante so that the President may pick negotiating partners, set terms of accords, sign and enter into them, draft implementing bills that advise the congressional process, and subject ultimate agreements to Congress with circumscribed ability to debate, no amendments, and abbreviated periods for up-or-down votes.<sup>42</sup> This was the approach for the original North American Free Trade Agreement in 1993 and its revision as the USMCA in 2018.

Such authority could be added to legislation currently circulating in Congress aimed at addressing pandemic preparedness and response. The Global Health Security Act of 2021 provides for activities to be conducted acting through the Director of the Centers for Disease Control and Prevention to combat SARS-CoV-2, COVID-19, and other emerging infectious disease threats globally, including efforts related to global health security, global disease detection and response, global health protection, global immunization, and global coordination on public health.<sup>43</sup>

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<sup>39</sup> David Wirth, *Is the Paris Agreement on Climate Change a Legitimate Exercise of the Executive Agreement Power?* Available at <https://www.lawfareblog.com/paris-agreement-climate-change-legitimate-exercise-executive-agreement-power>

<sup>40</sup> W. MC CLURE, INTERNATIONAL EXECUTIVE AGREEMENTS 41, 83–92, 173–89 (1941).

<sup>41</sup> See Trade Expansion Act of 1962, 76 Stat. 872, § 201, 19 U.S.C. § 1821; Trade Act of 1974, 88 Stat. 1982, as amended, 19 U.S.C. §§ 2111, 2115, 2131(b), 2435.

<sup>42</sup> 19 U.S.C. §§ 2191–2194.

<sup>43</sup> H.R.391 — 117th Congress (2021-2022)

### C. Sole Executive Agreements

Since at least 1996, the U.S. President has issued executive orders tying his authority over national security determinations to the threat posed by infectious diseases. In that year, President Bill Clinton identified new and emerging infectious diseases as a national security threat, ordered interagency cooperation to be led by the U.S. Centers for Disease Control and Prevention. Most importantly, the order committed the U.S. to the revision of the International Health Regulations, at that time a relatively limited international instrument committed to the surveillance and quarantine of only six diseases.<sup>44</sup>

On his first day in office, President Biden issued an executive order requiring the Assistant to the President for National Security Affairs (APNSA) to “coordinate the Federal Government’s efforts to address such threats and to advise the President on the global response to and recovery from COVID-19, including matters regarding: the intersection of the COVID-19 response and other national security equities; global health security; engaging with and strengthening the World Health Organization; public health, access to healthcare, and the secondary impacts of COVID-19; and emerging biological risks and threats, whether naturally occurring, deliberate, or accidental.”<sup>45</sup>

The world’s most developed international infectious disease agreement, the International Health Regulations (2005), was joined by the United States on the basis of its membership in the World Health Organization, and that body’s authority under Article 21 of its Constitution to adopt regulations in specific areas of international health delegated to it. Arguably, the U.S. participation in the IHR (2005) included tacit authorization from Congress as well. Because Congress authorized the U.S. entry into the WHO, there was no subsequent need for the President to independently seek Congressional authorization for the IHR’s adoption.

Even had Congress not played a background role, the U.S. joined the IHR (2005) out of national security interests articulated by the U.S. Over the course of the late 1990s and early 2000s, infectious disease threats to global security proliferated as did efforts to hide or obfuscate them.<sup>46</sup> The resurgence of cholera in South America, plague in India, and Ebola in Africa, as well as the emergence of HIV as a global pandemic, encouraged global unity in the belief that an international agreement was needed to address local infectious disease outbreaks that increasingly crossed international borders.<sup>47</sup> In January 2000, the UN Security Council recognized for the first time an infectious disease, HIV/AIDS, as an international peace and security matter. The precursor to the Security Council debate [in 2000] was a U.S. National Intelligence assessment of the security threat posed by infectious diseases. The National Intelligence Council report emphasized potential ramifications on international stability: “the persistent infectious disease burden is likely to aggravate and, in

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<sup>44</sup> 1996 Presidential Decision Directive on emerging diseases available at <https://irp.fas.org/offdocs/pdd/pdd-nstc-7.pdf>

<sup>45</sup> <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-organizing-and-mobilizing-united-states-government-to-provide-unified-and-effective-response-to-combat-covid-19-and-to-provide-united-states-leadership-on-global-health-and-security/>

<sup>46</sup> Don Noah & George Fidas, *The Global Infectious Disease Threat and Its Implications for the United States*, 99-17(D) NATIONAL INTELLIGENCE ESTIMATE 1, 5 (Jan. 2000), [https://www.dni.gov/files/documents/infectiousdiseases\\_2000.pdf](https://www.dni.gov/files/documents/infectiousdiseases_2000.pdf); (“New and reemerging infectious diseases will pose a rising global health threat and will complicate US and global security over the next 20 years.”); David E. Bloom & Daniel Cadarette, *Infectious Disease Threats in the Twenty-First Century: Strengthening the Global Response*, 10 FRONTIERS IN IMMUNOLOGY (Mar. 28, 2019) (“While rapid transmission of resistant pathogens is unlikely to occur in the same way it may with pandemic threats, the proliferation of superbugs is making the world an increasingly risky place.”).

<sup>47</sup> See, e.g., Sam Halabi, Rebecca Katz & Amanda McClelland, *International Institutions and Ebola Response: Learning from the 2017 Outbreak in the Democratic Republic of Congo*, 88 ST. LOUIS U. L.J. 1, 4 (2019).

some cases, may even provoke economic decay, social fragmentation and political destabilization of the hardest hit countries in the developing world.”<sup>48</sup>

The President therefore possesses significant independent authority under the U.S. Constitution to address global disease threats to international security, although, as outlined above, the President is limited with respect to his ability to dedicate financial resources. Indeed, the IHR (2005) itself *does* require commitments to health system strengthening, advanced disease surveillance, and regulation of ports of entry, but the U.S. already had those systems in place when it joined. Outside of core disease detection and response capacities, the IHR (2005) largely committed the U.S. to information sharing, which has long been a proper source for sole executive action.

### III. The Content of the Pandemic Treaty and the Legal Pathways for U.S. Participation

The components of a pandemic treaty are still under intense negotiation. At the very least, such a treaty would include provisions related to surveillance for new and reemerging pathogens, access to vaccines, international biosafety, an international system for monitoring and compliance, and information sharing with respect to a number of classes of data including research on diagnostics, therapeutics and vaccines.<sup>49</sup> Each of these aspects of the pandemic treaty will implicate a variety of sources of legal authority for the President to consult, if, as is likely, there is not sufficient support in the U.S. Senate for a binding treaty under Article II of the U.S. Constitution. The following issues have been frequently raised and, while not exhaustive, provide a representative list of issues the Executive will need to consider using the constitutional framework articulated above.

#### A. Biosafety

The two leading theories as to COVID-19’s origin are a spillover event from one mammalian species through another to humans and a leak from a biomedical research facility. Without engaging in the protracted debate as to origin of SARS-CoV-2 and prevention of future pandemics, an international agreement, even a non-binding one, may better prepare the world for the possibility of breaches in biosafety research with international ramifications. There are a finite number of research facilities worldwide that manage dangerous pathogens generally characterized as BSL-3 or BSL-4 in the laboratory context.<sup>50</sup> There are already published international guidance documents governing biosafety practices that may be codified in an international agreement, including inspection and early warning technologies.<sup>51</sup>

With respect to U.S. participation, biosafety is an area where the President enjoys significant treaty and statutory authority. For example, the U.S. is already a party to the 1972 Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction (Biological Weapons Convention), so any aspect of a pandemic treaty that implicated a dedicated corps of inspectors for so-called “dual-use” research would provide an independent source of authority for

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<sup>48</sup> Alex de Waal, *The Art of Medicine: HIV/AIDS and the Challenges of Security and Conflict*, 375 LANCET 22, 22 (2010).

<sup>49</sup> Gostin, Halabi, and Klock, *supra* note 8.

<sup>50</sup> World Health Organization, Laboratory Biosafety Manual, available at <https://www.who.int/csr/resources/publications/biosafety/Biosafety7.pdf>

<sup>51</sup> *Id.*

the U.S. to join.<sup>52</sup> The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 similarly authorizes a number of measures the President, the Secretary of Health and Human Services and the Secretary of Agriculture may take with respect to international partners and organizations with respect to biosafety.<sup>53</sup>

## B. Vaccine Access

The inequitable access and distribution of COVID-19 vaccines constitutes the most important challenge facing the global COVID-19 response. Low- and middle-income countries asked to coordinate with wealthier countries and international organizations have lost nearly all trust in international legal instruments and actors as the investments they made in the International Health Regulations (2005) core capacities still did not result in access to the most important medical intervention. Although both governments and public health professionals have confirmed that the world cannot fully reopen until the global population reaches herd immunity, wealthy countries continue to hoard vaccines and related technology.

The President's authority over sharing finished vaccine doses (as opposed to the technology that makes them possible discussed below) is shaped by international agreements (although not an Article II treaty) and existing statutory frameworks. The Defense Production Act authorizes the president, largely through executive order, to direct private companies to prioritize orders from the federal government.<sup>54</sup> The president is also empowered to "allocate materials, services, and facilities" for national defense purposes, and take actions to restrict hoarding of needed supplies. To bolster domestic production, the president may also offer loans or loan guarantees to companies, subject to an appropriation by Congress; make purchases or purchase commitments; and install equipment in government or private factories.<sup>55</sup> As Rizvi and Kapczynski write, the scope of the DPA has expanded since its World War II origins, to include "'military or critical infrastructure assistance to any foreign nation,' and 'critical infrastructure assistance and protection' (which includes systems and assets, the degradation of which would have a debilitating impact on 'national public health'), as well as 'emergency preparedness activities.'"<sup>56</sup>

In 2011, the U.S. acceded to the Pandemic Influenza Preparedness Framework, which authorized the World Health Organization to enter into agreements with academic institutions and pharmaceutical companies.<sup>57</sup> In exchange for access to influenza samples submitted to the World Health Organization's Global Influenza Surveillance and Response System, companies agree to donate real-time production of vaccines. Currently, the agreement is limited to "pandemic influenza" but part of the treaty negotiations may expand the agreement to include all pathogens with pandemic potential.<sup>58</sup> As of 2021, 71 SMTAs had been entered into by the WHO, 29 of which promised benefits like real-time vaccine production. The U.S. could join other Member States to expand the PIP Framework to cover all pathogens with pandemic potential.

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<sup>52</sup> D.Schindler and J.Toman, *THE LAWS OF ARMED CONFLICTS*, 137-142 (1988).

<sup>53</sup> Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (P.L. 107-188).

<sup>54</sup> THE DEFENSE PRODUCTION ACT. OF 1950, AS AMENDED. [50 U.S.C. § 4501 et seq.]

<sup>55</sup> Anshu Siripurapu, What is the Defense Production Act? Council on Foreign Relations, Jan. 26, 2021 available at <https://www.cfr.org/in-brief/what-defense-production-act>

<sup>56</sup> "Sharing The Knowledge: How President Joe Biden Can Use The Defense Production Act To End The Pandemic Worldwide," Health Affairs Blog, August 6, 2021. DOI: 10.1377/hblog20210804.101816

<sup>57</sup> The PIP Framework was enacted through an Article 23 WHA Recommendation. Those are generally achieved through consensus. The U.S. joined this consensus. <https://www.ncbi.nlm.nih.gov/books/NBK544063/>

<sup>58</sup> World Health Assembly, Res. WHA60.28, Pandemic influenza preparedness: sharing of influenza viruses and access to vaccines and other benefits.

Not only could the U.S. join an Article 23 consensus expansion of the PIP Framework to all pathogens, as it did with the initial agreement, but it could use its statutory authority over technologies developed with its support to require that they do so. Pursuant to the U.S. Bayh-Dole Act of 1980, for example, inventions that receive federal funding belong to the U.S. government unless the recipients commit to commercialize the invention and agree to the government's reservation of certain rights.<sup>59</sup> These include rights to protect the public against non-use or unreasonable use of publicly funded inventions.<sup>60</sup> One right is the government's non-transferable right to royalty free use of publicly funded inventions for or on behalf of the United States.<sup>61</sup>

Under the Bayh-Dole Act, march-in rights are only to be used when (1) the contractor fails to take effective steps to achieve practical application of the invention or (2) they are necessary to alleviate health or safety needs which are "not reasonably satisfied".<sup>62</sup> No administration or executive agency has ever used these march-in rights and there has never been a successful petition for the use of march-in rights in the four decades of their existence.<sup>63</sup> However, they may serve as a basis for U.S. support of such provisions in a new international agreement.<sup>64</sup>

### C. Intellectual Property

COVID-19 vaccines, especially the most efficacious of them produced in Europe and North America, are protected by a range of intellectual property protections: patents, trade secrets, and proprietary know-how essential to low-cost manufacturing elsewhere. Although further upstream from the finished doses, the President enjoys wider authority over the intellectual property protections that cover the ability to develop downstream diagnostics, therapeutics, and vaccines now concentrated in the wealthier countries of Europe, North America, and East Asia. One of the obvious ways to address intellectual property barriers to COVID-19 vaccine access is to, temporarily or permanently, do away with intellectual property protections for the technologies used to produce them. TRIPS, the international agreement establishing high floors for intellectual property protection, for example 20-year protections for patents, is one of the most important of these barriers.

When Congress authorized the U.S. to join TRIPS, it also allowed the President to waive provisions of the agreement without expressly requiring congressional action or approval before the U.S. Trade Representative agreed to such waivers. Instead, if a proposed waiver "would substantially affect the rights or obligations of the United States under the WTO Agreement . . . or potentially entails a change in Federal or State law," then USTR must consult with the "appropriate congressional committees" before any vote on the proposed waiver in the Ministerial Conference or General Council. Those "appropriate congressional committees" are the House Ways and Means and Senate Finance Committees. If the Ministerial Conference or General Council adopts a proposed waiver, the USTR must submit a report discussing the waiver to those congressional committees and consult with them about the waiver.

So the President is authorized under current statute to issue broad waivers with respect to intellectual property protections for vaccine technologies. While there may be additional, complicating political factors,

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<sup>59</sup> *Stanford University v. Roche Molecular Systems, Inc.*, 563 U.S. 776 (2011); Jordan Paradise. COVID-IP: staring down the Bayh-Dole Act with 2020 vision. *Journal of Law and the Biosciences*, 1–13doi:10.1093/jlb/lisaa07

<sup>60</sup> <https://www.nytimes.com/2021/09/22/us/politics/covid-vaccine-moderna-global.html>

<sup>61</sup> William O'Brien, *March in Rights Under the Bayh-Dole Act: The NIH's Paper Tiger?* 43 SETON HALL LAW REVIEW, 1404 (2013).

<sup>62</sup> *Id.*

<sup>63</sup> *Id.*

<sup>64</sup> Kuan, Stephenson, Wang, *Life Sciences Considerations Regarding Compulsory Licensing, March-In Rights, and the Defense Production Act During COVID-19*, 33 INTELLECTUAL PROPERTY & TECHNOLOGY LAW JOURNAL 11 (2021).

especially from domestic constituencies, this aspect of U.S. engagement is already codified Presidential authority.

#### D. Information Sharing

In order to even assess likely threats to national security and to perform functions envisioned by Article II of the U.S. Constitution, the President must have authority to information. The President has virtual plenary authority with respect to information necessary to inform national security decisions.<sup>65</sup> Presidents also rely on other clauses to support their foreign policy actions, particularly those that bestow “executive power” and the role of “commander in chief of the army and navy” on the office. From this language springs a wide array of associated or “implied” powers. For instance, from the explicit power to appoint and receive ambassadors flows the implicit authority to recognize foreign governments and conduct diplomacy with other countries generally. From the commander-in-chief clause flow powers to use military force and collect foreign intelligence.

In *U.S. v. Curtiss-Wright Corporation*, the U.S. Supreme Court held that President Franklin D. Roosevelt acted within his constitutional authority when he brought charges against the Curtiss-Wright Export Corporation for selling arms to Paraguay and Bolivia in violation of federal law. The president is “the sole organ of the federal government in the field of international relations,” Justice Sutherland wrote on behalf of the court. “He, not Congress, has the better opportunity of knowing conditions which prevail in foreign countries and especially is this true in time of [national emergencies]”.<sup>66</sup>

Similarly, in the negotiations leading to the U.S. joining the Paris Climate Accords in 2016, the U.S. felt at maximum Article II authority in the context of information sharing. Many of the binding obligations in the Paris Agreement involve reporting of emissions, progress in implementation, and accounting for emissions. Exchanging information with other states is a Constitutional power of the President as Chief Executive and the U.S.’s top diplomat, the “sole organ” of the Nation in dealing with foreign governments. Even in the absence of express statutory or treaty authority, the President may engage in information exchange and cooperation with foreign governments.<sup>67</sup>

## IV. Conclusion

The outcome of the World Health Assembly for the United States will depend not only on the priorities given to certain weaknesses in the global legal framework leading to the COVID-19 pandemic, but the constitutional framework that shapes the legal possibilities for what the President is authorized to include. As this Essay has shown, a pandemic treaty, at least one achieved through Presidential signature and two-thirds concurrence by the Senate, is not likely. However, there is a significant body of law developed by Congress dating back to the U.S. entry into the World Health Organization as well as independent executive authority to open possibilities for the U.S. contributing to, and one day joining, a legally-binding international agreement on pandemic prevention and response.

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<sup>65</sup> Department of the Navy v. Egan, 484 U.S. 518 (1988); James A. Baker, Intelligence Oversight, 45 HARV. J. ON LEGIS. 199, 202-03 (2008); James E. Baker, IN THE COMMON DEFENSE: NATIONAL SECURITY LAW FOR PERILOUS TIMES 146 (2007). But see Louis Fisher, Congressional Access to National Security Information, 45 HARV. J. ON LEGIS. 219, 230-32 (2008).

<sup>66</sup> United States v. Curtiss-Wright Export Corp., 299 U.S. 304 (1936).

<sup>67</sup> See e.g. Memorandum of Intent Between the Government of the United States of America and the Government of Canada Concerning Transboundary Air Pollution, Washington, 1980.