

**EXECUTIVE AUTHORITY UNDER THE U.S.
CONSTITUTION TO ENTER A PANDEMIC
TREATY OR OTHER INTERNATIONAL
AGREEMENT**

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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.¹ For children, long COVID occurs for approximately ten to thirteen percent of cases, imposing potentially life-long disability.² Economically, the productivity, job loss, and response costs exceed sixteen trillion dollars in the United States alone.³ The International Monetary Fund estimates that, through October 2020, the global cost stood at twenty-eight trillion dollars.⁴ Supply chain disruptions now vex every

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¹ Daniel E. Slotnik, *The World’s Known Covid Death Toll Passes Four Million.*, N.Y. TIMES (July 8, 2021), <https://www.nytimes.com/2021/07/08/world/covid-death-toll-four-million.html>; *Total number of global cases of coronavirus surpasses 219 million*, INTER PRESS NEWS (Sep. 2, 2021, 10:17 AM), <https://www.interpressnews.ge/en/article/115416-total-number-of-global-cases-of-coronavirus-surpasses-219-million>.

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

³ David M. Cutler & Lawrence H. Summers, *The COVID-19 Pandemic and the \$16 Trillion Virus*, JAMA (Oct. 12, 2020), <https://jamanetwork.com/journals/jama/fullarticle/2771764>.

⁴ Larry Elliott, *IMF Estimates Global Covid Cost at \$28tn in Lost Output*, THE GUARDIAN (Oct. 13, 2020), <https://www.theguardian.com/business/2020/oct/13/imf-covid-cost-world-economic-outlook>.

country in the world.

Nearly all governments agree that the numbers reflect a world that was poorly prepared when the new pathogen emerged and struggled to coordinate its response after the threat became clear. As a result, full recovery may be delayed by a decade or more.⁵ While vaccination rates have climbed to herd immunity thresholds in the wealthiest countries, ninety-five percent of the world's population in low-income countries does not have access to a first dose.⁶ The World Health Organization ("WHO") 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) ("IHR"), adopted after the global experience with SARS-CoV-1 in 2002–03.⁷

Governments further agree that better coordination and communication between governments is necessary, but disagree on the form that improved coordination and communication should take. On March 30, 2021, the leaders of twenty-six countries, the WHO 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.⁸ In May 2021, the seventy-fourth session of the World Health Assembly took the extraordinary measure of

⁵ ORG. FOR ECON. CO-OP. & DEV., CORONAVIRUS (COVID-19) VACCINES FOR DEVELOPING COUNTRIES: AN EQUAL SHOT AT RECOVERY 5, 10–11 (2021), https://read.oecd-ilibrary.org/view/?ref=1060_1060300-enj5o5xnwj&title=Coronavirus-COVID-19-vaccines-for-developing-countries-An-equal-shot-at-recovery.

⁶ Anna Rouw et al., *Tracking Global COVID-19 Vaccine Equity*, KAISER FAM. FOUND. (Jul. 21, 2021), <https://www.kff.org/coronavirus-covid-19/issue-brief/tracking-global-covid-19-vaccine-equity/>.

⁷ Stephen T. Green & Lorenzo Cladi, *Rapid Response: Should the WHO's Chronic Disempowerment and Impecuniousness Concern Us?*, *BMJ* (Apr. 27, 2020), <https://www.bmj.com/content/369/bmj.m1502/rr-1>.

⁸ Lawrence O. Gostin, Sam F. Halabi & Kevin A. Klock, *An International Agreement on Pandemic Prevention and Preparedness*, *JAMA* (Sept. 15, 2021), <https://jamanetwork.com/journals/jama/fullarticle/2784418>.

calling a Special Session, scheduled for November 29–December 1, 2021, to consider precisely such a legal instrument.⁹ The United States has remained circumspect with regard to a formal treaty, publicly articulating support for a revision of the IHR (2005) and some improvements to governance, for example, more transparent decision-making about the declaration of emergencies and recommended measures, at the WHO, while remaining open to the development of a new international agreement.¹⁰ This Essay aims to clarify what the United States may and may not do under its domestic constitutional framework, both to inform its global partners and to shed light on how the U.S. Constitution structures international affairs during emergencies.

This analysis prioritizes what is possible. What the United States ultimately determines is in the interest of its citizens may differ. The United States, for example, may simply determine 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.¹¹ Any visibility as to vaccine access and equity would cast the United States in a poor light, to say nothing of the substantive provisions of a treaty addressing vaccine access, which could affect the profitability and flexibility of companies based in the United States. Over the course of the pandemic, U.S.-based companies developed three of the four most successful vaccines and, in its contracts for their

⁹ World Health Org. [WHO], *Special Session of the World Health Assembly to Consider Developing a WHO Convention, Agreement or Other International Instrument on Pandemic Preparedness and Response*, ¶ 3, A74/A/CONF.7 (May 25, 2021), https://apps.who.int/gb/ebwha/pdf_files/WHA74/A74_ACONF7-en.pdf.

¹⁰ Anthony J. Blinken & Xavier Becerra, *Strengthening Global Health Security and Reforming the International Health Regulations*, JAMA (Aug. 31, 2021), <https://jamanetwork.com/journals/jama/fullarticle/2783866>.

¹¹ WHO, *supra* note 9, ¶ 1; *The World Must Learn from COVID before diving into a Pandemic Treaty*, 592 NATURE 165, 65–66 (noting the prominence of vaccine access as one of four key areas the pandemic treaty must address).

procurement, the U.S. government prohibited the possibility that doses might be shipped elsewhere, even to those countries that may be in desperate need.¹² The United States 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.¹³ The United States may also be staking out a preliminary position of neutrality, so that even its willingness to join may secure benefits from its participation in negotiation.¹⁴

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, with an important role for Congress, and much less so the U.S. Supreme Court.¹⁵ Article I vests Congress with authority over most matters that require the raising and expenditure of revenues, the regulation of the armed forces, the definition of the content and relevance of international law, and the regulation of foreign commerce.¹⁶

Article II vests authority with the President to negotiate treaties, although two-thirds of the Senate must concur with

¹² Katherine Eban, “We Are Hoarding”: *Why the U.S. Still Can’t Donate COVID-19 Vaccines to Countries in Need*, VANITY FAIR (Apr. 6, 2021), <https://www.vanityfair.com/news/2021/04/why-the-us-still-cant-donate-covid-19-vaccines-to-countries-in-need>.

¹³ U.S. Proposal on Targeted Amendments to the International Health Regulations, 2021 (policy position on file with author).

¹⁴ 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. See Antonia Chayes, *How American Treaty Behavior Threatens National Security*, 33 INT’L SEC. 45 (2008). The U.N. Convention on the Law of the Sea is an archetypal case of such behavior. *Id.* See also U.S. Signature to the 1998 Rome Statute of the International Criminal Court (Dec. 31, 2000) (noting that the United States was signing with the intention to further influence the drafting of the final text).

¹⁵ See, e.g., *United States v. Curtiss-Wright Exp. Corp.*, 299 U.S. 304 (1936); *Youngstown Sheet & Tube Co. v. Sawyer*, 343 U.S. 579, 634–55 (1952) (Jackson, J., concurring).

¹⁶ U.S. CONST. art. I, § 8.

the treaty text in order for it to become law.¹⁷ Separately, Article II authorizes the Executive to “receive Ambassadors,” which is generally interpreted to mean that the President is entrusted with the authority to recognize foreign governments and relatedly, conduct diplomacy.¹⁸ The President is also the Commander-in-Chief, giving him independent authority with respect to national security.¹⁹

With respect to the judiciary, Article III dedicates to the U.S. Supreme Court original jurisdiction over certain matters affecting foreign relations, but the Court largely plays a peripheral role in the formation and execution of foreign policy and avoids adjudication of “political questions” about foreign policy dedicated to Congress and the President.²⁰ 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.²¹

Despite the availability of a specific constitutional mechanism to govern treaty relations, the presidentially negotiated, Senate-confirmed treaty has fallen into desuetude. Since the Franklin D. Roosevelt administration, only six percent of international agreements have gone through the Senate ratification process.²² While the last

¹⁷ *Id.* art. II, § 2.

¹⁸ *Id.* § 3.

¹⁹ *Id.* § 2.

²⁰ LOUIS HENKIN, FOREIGN AFFAIRS AND THE CONSTITUTION 26–27 (1972); *Atlee v. Richardson*, 411 U.S. 911 (1973), *aff’g* *Atlee v. Laird*, 347 F. Supp. 689 (E.D. Pa. 1972).

²¹ *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. *See id.* at 998–1001 (Powell, J., concurring). 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.

²² CONG. RSCH. SERV., TREATIES AND OTHER INTERNATIONAL AGREEMENTS: THE

Senate-confirmed treaty was the New START treaty with Russia, other agreements have been adopted through both chambers of Congress with the support of more than two-thirds of the Senate.²³ 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.²⁴

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 United States 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).²⁵ 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.

The purpose of this Essay is to identify how the United States may join an international pandemic agreement,

ROLE OF THE UNITED STATES SENATE 39 (2001), <https://www.govinfo.gov/content/pkg/CPRT-106SPRT66922/pdf/CPRT-106SPRT66922.pdf>.

²³ See, e.g., Free Trade Agreement, S. Kor.-U.S., Jun. 30, 2007, <https://ustr.gov/trade-agreements/free-trade-agreements/korus-fta>.

²⁴ Elaine Ruth Fletcher, *United States Holds Back on Bold Move Toward Pandemic Treaty*, HEALTH POLY WATCH (May 21, 2021), <https://healthpolicy-watch.news/exclusive-us-still-holding-back-on-bold-move-toward-pandemic-treaty/>.

²⁵ 42 U.S.C. §§ 7401–7671.

especially when both congressional chambers are so evenly divided, and one party has so clearly expressed its pessimism about a pandemic treaty as well as international agreements in general, leaving the most likely constitutional pathways presidential action based in existing statutory authorizations or the exercise of sole presidential authority under the U.S. Constitution.²⁶

I. THE U.S. CONSTITUTIONAL FRAMEWORK

This Part analyzes the constitutional framework for how the U.S. may enter into international agreements: the dedicated treaty process between the President and the Senate; explicit and implicit agreement between the President and both congressional chambers; and sole executive authority based on Article II powers.

A. Treaties

The U.S. Constitution authorizes the President to “make Treaties” provided that “two thirds of the Senators present concur.”²⁷ Once properly adopted, treaties become binding federal law, just like statutes adopted through bicameral deliberation and signature by the President.²⁸ 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

²⁶ 22 U.S.C. § 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.”).

²⁷ U.S. CONST. art. II, § 2.

²⁸ *Id.* art. VI.

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 United States to international partners including both foreign governments and international organizations.²⁹

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 United States internationally, they also addressed different forms of international agreement, particularly in Article I.³⁰ The treaty process was intentionally arduous given the potential to create federal law without the House of Representatives.³¹ Agreements made with the consent of the Senate are historically rare. Nearly ninety percent of international agreements (approximately 15,000 agreements) that the United States has entered since World War II have been approved outside the constitutional treaty process.³²

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 United

²⁹ See *Asakura v. City of Seattle*, 265 U.S. 332, 342–43 (1924).

³⁰ Suzanna Sherry, *The Founders' Unwritten Constitution*, 54 U. CHI. L. REV. 1127, 1137 (1987).

³¹ 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. *Missouri v. Holland*, 252 U.S. 416 (1920). 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. *Bond v. United States*, 572 U.S. 844, 858–61 (2014).

³² Nigel Purvis, *The Case for Climate Protection Authority*, 49 VA. J. INT'L L. 1007, 1018 (2009).

States used from its earliest years as a constitutional republic. Fifty years from its founding, the United States concluded nearly thirty published executive agreements outside of the treaty process.³³

These other forms of approving 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 enforced³⁴ and pursuant to responsibilities collectively understood as the President's foreign affairs power.³⁵ 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.³⁶

1. *Current Statutory Authority*

When Congress adopts statutes, they may and often do shape the President's authority to conduct diplomacy, for example authorizing sanctions, or encouraging support of international organizations. Congress has adopted a number of statutory provisions that authorize the President to undertake broad coordinating action to advance global health. Current statutory authorizations include language that the President, Secretary of State, and Secretary of Health and Human Services may consult when deliberating the content of an international pandemic agreement.

³³ Peter L. Fitzgerald, *Executive Agreements and the Intent Behind the Treaty Power*, 2 HASTINGS CONST. L.Q. 757, 758 (1975).

³⁴ U.S. CONST. art II, § 3.

³⁵ See *id.* §§ 1–3; U.S. DEP'T OF STATE, 11 FOREIGN AFFAIRS MANUAL § 723.2-2(C) (2006).

³⁶ See *Annotation 12 – Article II*, FINDLAW, <https://constitution.findlaw.com/article2/annotation12.html> (last visited Mar. 23, 2022).

For example, when Congress authorized the United States to join the WHO, it recognized the “widespread prevalence, debilitating effects, and heavy toll in human life” of the “diseases of mankind,” and declared “it to be the policy of the United States to continue and strengthen mutual efforts among the nations for research against [such] diseases.”³⁷

Moreover, 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.”³⁸ 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 United States to engage and support international organizations and partners with respect to national security threats posed by infectious and anti-microbial resistant diseases.³⁹ All of this language could be used to justify specific commitments under a pandemic treaty.

This is almost precisely how President Obama joined the Paris Climate Accords in in 2016 (and how President Biden anchored rejoining in 2021). In negotiating the Paris Agreement, the Executive Branch based its authority upon (1) the President’s plenary constitutional power in the foreign affairs field; (2) federal legislation, particularly the Clean Air Act; and (3) existing treaties, most importantly the 1992 Framework Convention on Climate Change, which the

³⁷ 22 U.S.C. § 290e.

³⁸ United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003, 22 U.S.C. 7604, § 101(a)(3).

³⁹ Pandemic and All-Hazards Preparedness Act, Pub. L. No. 109-417, 120 Stat. 2831 (2006); Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019, Pub. L. No. 116-22, 133 Stat. 905 (2019).

United States under President George H.W. Bush joined with relatively rapid Senate consent.⁴⁰ The text of the Paris Agreement distinguishes between the mandatory “shall”—indicating binding legal obligations—and the precatory “should”—indicating non-binding political statements.⁴¹ The U.S. delegation succeeded in tailoring the text to the scope of the President’s constitutional exercise of his authority as it was then interpreted.⁴²

2. *Advanced Congressional Authorization*

Congress may also authorize the President’s conduct of diplomacy in advance. While current statutory authority provides one body of law through which the President may shape pandemic treaty provisions, an alternative route is to obtain advance authorization from Congress, by simple majorities, for broad authority leading to the pandemic negotiations.⁴³ This is how trade agreements have been concluded for over a century.⁴⁴ In 1890, Congress authorized the President to bargain over reciprocity in tariff reductions with foreign governments with no requirement of subsequent legislative implementation.⁴⁵ 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.⁴⁶

Congress could also adopt so-called fast-track authority used for more current international trade agreements. Fast-

⁴⁰ David A. Wirth, *Is the Paris Agreement on Climate Change a Legitimate Exercise of the Executive Agreement Power?*, LAWFARE (Aug. 29, 2016), <https://www.lawfareblog.com/paris-agreement-climate-change-legitimate-exercise-executive-agreement-power>.

⁴¹ *Id.*

⁴² *Id.*

⁴³ Jean Galbraith, *Prospective Advice and Consent*, 37 YALE J. INT’L L. 247, 283 (2012).

⁴⁴ WALLACE MCCLURE, INTERNATIONAL EXECUTIVE AGREEMENTS 41, 83–92, 173–89 (1941).

⁴⁵ Tariff Act of 1890, § 3, 26 Stat. 567, 612.

⁴⁶ See Trade Expansion Act of 1962, 19 U.S.C. § 1821; Trade Act of 1974, as amended, 19 U.S.C. §§ 2111, 2115, 2131(b), 2435.

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, limit debate, prohibit amendments, and abbreviate periods for up-or-down votes.⁴⁷ This was the approach for the original North American Free Trade Agreement in 1993 and its revision as the United States-Mexico-Canada Agreement in 2018.⁴⁸

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, disease detection and response, health protection, immunization, and coordination on public health.⁴⁹

C. Sole Executive Agreements

Finally, the President enjoys authority under Article II to conduct foreign relations without any congressional authorization. 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 1996, President Bill Clinton identified new and emerging infectious diseases as a national security threat and ordered interagency cooperation led by the U.S. Centers for

⁴⁷ 19 U.S.C. §§ 2191–2194.

⁴⁸ Laura Wright, *Trade Promotion Authority; Fast Track for the Twenty-First Century*, 12(3) WM. & MARY BILL RTS. J. 979, 987 (2004) (analyzing this authority for NAFTA); Lisa M. Richman, *The Investment Treaty Arbitration Review: NAFTA and USMCA: The Next Stage of the Saga*, THE L. REVS. (June 18, 2021), <https://thelawreviews.co.uk/title/the-investment-treaty-arbitration-review/nafta-and-usmca-the-next-stage-of-the-saga> (analyzing the authority for USMCA).

⁴⁹ Global Health Security Act of 2021, H.R. 391, 117th Cong. (2021).

Disease Control and Prevention.⁵⁰ Most importantly, the order committed the United States to the revision of the IHR, at that time a relatively limited international instrument committed to the surveillance and quarantine of only six diseases.⁵¹

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.”⁵²

The United States joined the world’s most developed international infectious disease agreement, the IHR (2005), 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.⁵³ Arguably, U.S. participation in the IHR included tacit authorization from Congress as well, but because Congress authorized 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 United States joined the IHR out of national security interests articulated by the Executive Branch. Over the

⁵⁰ Presidential Decision Directive on Emerging Diseases 2, 4, PDD/NSTC-7 (June 12, 1996), <https://irp.fas.org/offdocs/pdd/pdd-nstc-7.pdf>.

⁵¹ *Id.* at 5.

⁵² Exec. Order No. 13987, 86 Fed. Reg. 7019 (Jan. 20, 2021).

⁵³ Constitution of the World Health Organization art. 21, July 22, 1946, 62 Stat. 2679, 14 U.N.T.S. 185.

course of the late 1990s and early 2000s, infectious disease threats to global security proliferated, as did efforts to hide or obfuscate them.⁵⁴ 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.⁵⁵ In 2000, the U.N. Security Council recognized for the first time an infectious disease, HIV/AIDS, as an international peace and security matter.⁵⁶ The precursor to the Security Council's decision was the U.S. National Intelligence Council's report emphasizing potential ramifications on international stability, which stated that "the persistent infectious disease burden is likely to aggravate and in some cases, may even provoke economic decay, social fragmentation and political destabilization in the hardest hit countries in the developing . . . world[]."⁵⁷

The President therefore possesses significant independent authority under the U.S. Constitution to address

⁵⁴ Don Noah & George Fidas, *The Global Infectious Disease Threat and its Implications for the United States*, 99 NAT'L INTEL. ESTIMATE 1, 5 (2000), 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), <https://www.frontiersin.org/articles/10.3389/fimmu.2019.00549/full> ("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.")

⁵⁵ Sam Halabi, Rebecca Katz & Amanda McClelland, *International Institutions and Ebola Response: Learning from the 2017 Outbreak in the Democratic Republic of Congo*, 64 ST. LOUIS U. L.J. 91, 94 (2019).

⁵⁶ U.N. GAOR, 55th Sess., 4087 mtg., U.N. Doc. S/PV.4087 (Jan. 10, 2000); S.C. Res. 1308, preamble (July 17, 2000).

⁵⁷ NAT'L INTELLIGENCE COUNCIL, NIE 99-17D, THE GLOBAL INFECTIOUS DISEASE THREAT AND ITS IMPLICATIONS FOR THE UNITED STATES 9 (2000), https://www.dni.gov/files/documents/infectiousdiseases_2000.pdf; see also Alex de Waal, *The Art of Medicine: HIV/AIDS and the Challenges of Security and Conflict*, 375 LANCET 22, 22 (2010).

global disease threats to international security, although, as outlined above, he is limited with respect to his ability to dedicate financial resources. Indeed, the IHR itself *does* require commitments to strengthening the health system, advancing disease surveillance, and regulating of ports of entry, but the United States already had such systems in place when it joined.⁵⁸ Outside of core disease detection and response capacities, the IHR largely committed the United States to information sharing, which has long been a proper source for sole executive action.⁵⁹ The content and process of pandemic treaty negotiations will be shaped by current international agreements, including the IHR (2005), which the United States joined as a sole executive agreement through its accession to WHO authority.

II. 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.⁶⁰ 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

⁵⁸ International Health Regulations, art. 5 (surveillance), art. 28 (points of entry), Annex I (core capacities encompassing health systems), May 23, 2005, 2509 U.N.T.S. 79.

⁵⁹ *Id.* arts. 6–7 (notification and information sharing).

⁶⁰ Gostin, Halabi & Klock, *supra* note 8.

consider using the constitutional framework articulated above. The constitutional authorities described above will shape components of an agreement in the following ways.

A. Biosafety

The two leading theories regarding COVID-19's origin are that the virus was transmitted from mammalian species to humans or through 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.⁶¹ Published international guidance documents governing biosafety practices, such as inspection and early warning technologies,⁶² could be codified in an international agreement.

With respect to U.S. participation, biosafety is an area where the President enjoys significant treaty and statutory authority. For example, the United States 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, 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 the United States to join.⁶³ The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 similarly authorizes

⁶¹ See generally WORLD HEALTH ORG., LABORATORY BIOSAFETY MANUAL (3d ed. 2004), <https://www.who.int/csr/resources/publications/biosafety/Biosafety7.pdf>.

⁶² *Id.*

⁶³ THE LAWS OF ARMED CONFLICTS: A COLLECTION OF CONVENTIONS, RESOLUTIONS, AND OTHER DOCUMENTS 137–42 (Dietrich Schindler & Jiri Toman eds., 3d ed. 1988).

a number of measures the President, the Secretary of Health and Human Services, and the Secretary of Agriculture may take with international partners and organizations on biosafety matters.⁶⁴

B. Vaccine Access

The inequitable access to 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 IHR (2005) core capacities 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, is shaped by international agreements (although not Article II treaties) and existing statutory frameworks. The Defense Production Act authorizes the President, largely through executive orders, to direct private companies to prioritize orders from the federal government.⁶⁵ The President is also empowered to "allocate materials, services, and facilities" for national defense purposes, and take actions to restrict hoarding of needed supplies.⁶⁶ 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

⁶⁴ See, e.g., Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188, § 335(a)(4), 116 Stat. 594, 680 (2002).

⁶⁵ Defense Production Act of 1950, as Amended, 50 U.S.C. §§ 4501–4568.

⁶⁶ 50 U.S.C. §§ 4511–4512.

install equipment in government or private factories.⁶⁷ 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.’”⁶⁸

In 2011, the United States acceded to the Pandemic Influenza Preparedness Framework, which authorized the WHO to enter into agreements with academic institutions and pharmaceutical companies.⁶⁹ In exchange for access to influenza samples submitted to the WHO’s Global Influenza Surveillance and Response System, companies agree to donate real-time production of vaccines.⁷⁰ 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.⁷¹ As of 2021, seventy-one “standard material transfer agreements” (“SMTAs”) had been

⁶⁷ Anshu Siripurapu, *What Is the Defense Production Act?*, COUNCIL ON FOREIGN RELS. (last updated Dec. 22, 2021), <https://www.cfr.org/in-brief/what-defense-production-act>.

⁶⁸ Zain Rizvi, Jishian Ravinthiran & Amy Kapczynski, *Sharing The Knowledge: How President Joe Biden Can Use the Defense Production Act to End the Pandemic Worldwide*, HEALTH AFFS. (Aug. 6, 2021), <https://www.healthaffairs.org/doi/10.1377/forefront.20210804.101816/full/>.

⁶⁹ The PIP Framework was enacted through an Article 23 WHA Recommendation. Those are generally achieved through consensus. The U.S. joined this consensus. NAT’L ACADS. OF SCIS., ENG’G, & MED., *The Development of the PIP Framework: Global Lessons on Equity and Fairness for Pandemic Preparedness*, in EXPLORING LESSONS LEARNED FROM A CENTURY OF OUTBREAKS: READINESS FOR 2030 (A. Nicholson et al. eds., 2019), <https://www.ncbi.nlm.nih.gov/books/NBK544063/>.

⁷⁰ WORLD HEALTH ORG., PANDEMIC INFLUENZA PREPAREDNESS FRAMEWORK FOR THE SHARING OF INFLUENZA VIRUSES AND ACCESS TO VACCINES AND OTHER BENEFITS 34 (2nd ed. 2022); see also Sam F. Halabi, *Viral Sovereignty, Intellectual Property, and the Changing Global System for Sharing Pathogens for Infectious Disease Research*, 28(1) ANNALS HEALTH L. 101, 124 (2019)

⁷¹ See World Health Assembly, *Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccines and Other Benefits*, Res. WHA60.28 (May 23, 2007), https://www.who.int/csr/don/archive/disease/influenza/A60_R28-en.pdf.

entered into by the WHO, twenty-nine of which promised benefits like real-time vaccine production.⁷² The United States could join other Member States to expand the PIP Framework to cover all pathogens with pandemic potential.

Not only could the United States 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 U.S.-funded biomedical companies share products or know-how with a global system. 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.⁷³ These include rights to protect the public against non-use or unreasonable use of publicly funded inventions.⁷⁴ 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.⁷⁵

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."⁷⁶ 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

⁷² *Standard Material Transfer Agreements 2 (SMTA2)*, WORLD HEALTH ORG., [https://www.who.int/initiatives/pandemic-influenza-preparedness-framework/standard-material-transfer-agreement-2-\(smta2\)](https://www.who.int/initiatives/pandemic-influenza-preparedness-framework/standard-material-transfer-agreement-2-(smta2)) (last visited Mar. 23, 2022).

⁷³ Bd. of Trs. of the Leland Stanford Junior Univ. v. Roche Molecular Sys., Inc., 563 U.S. 776 (2011); Jordan Paradise, *COVID-IP: Staring down the Bayh-Dole Act with 2020 Vision*, 7 J. L. & BIOSCIENCES 1, 6 (2020).

⁷⁴ See Stephanie Nolen & Gay Stolberg, *Pressure Grows on U.S. Companies to Share Covid Vaccine Technology*, N.Y. TIMES (Sept. 22, 2021), <https://www.nytimes.com/2021/09/22/us/politics/covid-vaccine-moderna-global.html>.

⁷⁵ William O'Brien, *March-in Rights Under the Bayh-Dole Act: The NIH's Paper Tiger?*, 43 SETON HALL L. REV. 1403, 1404 (2013).

⁷⁶ *Id.*

in the four decades of their existence.⁷⁷ However, they may serve as a basis for U.S. support of such provisions in a new international agreement.⁷⁸

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. The President enjoys wide authority, however, over the intellectual property protections that cover the ability to develop downstream diagnostics, therapeutics, and vaccines now concentrated in the wealthier countries in 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. Agreement on Trade-Related Aspects of Intellectual Property Rights (“TRIPS”), the international agreement establishing high floors for intellectual property protection, for example twenty-year protections for patents, is one of the most important of these barriers.⁷⁹

When Congress authorized the United States 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 (“USTR”) agreed to such waivers. If a proposed waiver “would substantially affect the rights or obligations of the United States under the WTO Agreement . . . or potentially entails a

⁷⁷ *Id.* at 1404–05.

⁷⁸ See Roger Kuan, Lyric Stephenson & Joan Wang, *Life Sciences Considerations Regarding Compulsory Licensing, March-In Rights, and the Defense Production Act During COVID-19*, 33 INTELL. PROP. & TECH. L.J. 11 (2021).

⁷⁹ See generally, Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299 (1994).

change in Federal or State law,” then the USTR must first seek advice from “appropriate congressional committees” before it votes on the waiver in the WTO.⁸⁰ When the WTO approves a proposed waiver, the USTR submits a report describing the waiver to those congressional committees and consult with them regarding the report.⁸¹

As such, the President is authorized under the current governing statute to issue broad waivers with respect to intellectual property protections for vaccine technologies. While there may be additional, complicating political factors, especially from domestic constituencies (for example, pharmaceutical companies), 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, the President must have authority to gather, receive, and transmit information. The President has virtual plenary authority with respect to information necessary to inform national security decisions.⁸² 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

⁸⁰ 19 U.S.C. §3532(b) (1994).

⁸¹ 19 U.S.C. §3532(c), (d).

⁸² *Dep't of the Navy v. Egan*, 484 U.S. 518, 527 (1988); *see also* 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).

generally.⁸³ From the commander-in-chief clause flows the power to use military force and collect foreign intelligence.⁸⁴

In *United States v. Curtiss-Wright Corp.*, 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.⁸⁵ The President is “the sole organ of the federal government in the field of international relations,” Justice Sutherland wrote, on behalf of the Court.⁸⁶ “[H]e, not Congress, has the better opportunity of knowing the conditions which prevail in foreign countries, and especially is this true in time of [national emergencies].”⁸⁷ Thus, under *Curtiss-Wright*, the President’s authority under the Constitution during emergencies is plenary.

Under this and related precedents, the United States operated within maximum Article II authority in the context of information sharing under the Paris Climate Accords. Many of the binding obligations in the Paris Agreement involve reporting of emissions, progress in implementation, and accounting for emissions.⁸⁸ As explained above, exchanging information with other states is a Constitutional power of the President as Chief Executive and the United States’ top diplomat, or the “sole organ” of the Nation in

⁸³ Jennifer Trejo, Note, *In the Eyes of the President: Supreme Court Holds Executive Branch Has Exclusive Power to Recognize Foreign Sovereigns*, 69 SMU L. REV. 291, 291 (2016).

⁸⁴ Michael D. Ramsey & Steve I. Vladeck, *Common Interpretation: Commander in Chief Clause*, NAT’L CONST. CTR., <https://constitutioncenter.org/interactive-constitution/interpretation/article-ii/clauses/345> (last visited Mar. 23, 2022).

⁸⁵ *United States v. Curtiss-Wright Exp. Corp.*, 299 U.S. 304 (1936).

⁸⁶ *Id.* at 320.

⁸⁷ *Id.*

⁸⁸ *See, e.g.*, Paris Agreement to the United Nations Framework Convention on Climate Change, art. 4(8), Dec. 12, 2015, T.I.A.S. No. 16-1104 (“In communicating their nationally determined contributions, all Parties shall provide the information necessary for clarity, transparency and understanding in accordance with decision 1/CP.21 and any relevant decisions of the Conference of the Parties serving as the meeting of the Parties to this Agreement.”).

dealing with foreign governments. Therefore, even in the absence of express statutory or treaty authority, the President may engage in information exchange and cooperation with foreign governments.⁸⁹

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, a significant body of law dating back to the U.S. entry into the WHO and independent executive authority open up possibilities for the United States to contribute to, and one day join, a legally binding international agreement on pandemic prevention and response. The President may carefully analyze existing statutory authorities to shape the U.S. position on biosafety, intellectual property, and access to vaccines. With respect to the sharing of information, the President enjoys significant Article II authority to negotiate provisions without congressional authorizations. Together, these constitutional constraints will guide the U.S. position on one or more international agreements governing pandemics as well as the specific provisions within each of them.

⁸⁹ See, e.g., Memorandum of Intent Concerning Transboundary Air Pollution, Can.-U.S., Aug. 5, 1980, T.I.A.S. No. 9856.