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Defending Healthcare Workers Requires More Than 3M Can Give

AIDAN ELY^{†*}

INTRODUCTION

In 1922 after World War I, Russia transitioned into the Union of Soviet Socialist Republics (USSR), a federal socialist state. After World War II, in which the USSR and the Western powers were relative allies, public concerns about communism began to spread due to international events.¹ In particular, events in 1949 and 1950 prompted this concern such as the USSR's successful testing of a nuclear bomb, Communist Mao Zedong's takeover of China, and the start of the Korean War.² Observing this scene on the world stage, Congress realized that any arising conflict would likely present itself as "total war," meaning that the entire nation would need to be mobilized to equal (or ideally, exceed) the production power of a socialist state.³ The Soviet economy was designed for an age of mass production and mass armies,⁴ and the United States needed to be able to match the communist production capability if war became a reality. For this reason, the Defense Production Act of 1950 (DPA) was born. The DPA confers upon the President a broad set of authorities to influence domestic industry in the interest of national defense⁵ so that, when called upon, the industries of the United States can produce essential materials and products.⁶ "Though initially passed in response to the Korean War, the DPA is historically based on the War Powers Acts of World War II."⁷ Congress has since expanded the term *national defense* within the DPA. The scope of DPA authorities now extends beyond shaping United States military preparedness and capabilities to also encompass enhancing and supporting domestic

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¹ History.com Editors, *Red Scare*, HISTORY (Feb. 28, 2020), <https://www.history.com/topics/cold-war/red-scare>.

² *Id.*

³ Mark Harrison, *The Soviet Economy, 1917-1991: Its Life and Afterlife*, VOX CEPR POLICY PORTAL (Nov. 7, 2017), <https://voxeu.org/print/62263> (based on "a standard measure developed by political scientists to capture 'the ability of a nation to exercise and resist influence' in the world. By the 1970s ... the Soviet Union became the world's leading power.").

⁴ *Id.*

⁵ Defense Production Act of 1950, ch. 774, 64 Stat. 798 (1950) (codified as amended at 50 U.S.C. §§ 450-4568).

⁶ *Id.*

⁷ MICHAEL H. CECIRE & HEIDI M. PETERS, CONG. RSCH. SERV., R43767, THE DEFENSE PRODUCTION ACT OF 1950: HISTORY, AUTHORITIES, AND CONSIDERATIONS FOR CONGRESS (2020).

preparedness, response, and recovery from natural hazards, terrorist attacks, and other national emergencies.⁸ This note argues that the DPA can—and should—be used to address infectious disease epidemics and pandemics as a type of national emergency.

This proposal will explore the need for language to be added to the DPA. The proposed expansion would include additional executive powers to compel, or if need be, force private companies to share proprietary information related to the production of materials during national emergencies. The precedent of this sort of executive power begins with a case examination of the themes of the Justices' opinions in *Youngstown Sheet & Tube Co. v. Sawyer*.⁹ This note will proceed through an examination of the current language of the DPA, its enforceability, and what the government *could do right now* with the DPA's current language to help with the COVID-19 pandemic. This note will then highlight why the current language is not enough to keep the American people safe. Additionally, this analysis will also include and address actions taken by both former President Trump and current President Biden to combat the pandemic. The actions taken by both Presidents will be followed by a brief discussion of the impediments to enacting the language proposed in this note and other alternatives such as consensual licensure by companies, expansion of other laws, and increasing efficiency and utilization of the national stockpiles. Finally, this note proposes language to be added to the DPA as well as the potential impact of such additions.

The number and diversity of epidemic events has been increasing over the past [thirty] years, a trend that is only expected to intensify . . . Potentially catastrophic outbreaks may only occur every few decades, but highly disruptive regional and local outbreaks, such as the 2014 Ebola virus crisis in West Africa, are becoming more common and pose a major threat to lives and livelihoods . . . despite considerable progress, the world remains ill-prepared to detect and respond to outbreaks and is not prepared to respond to a significant pandemic threat.¹⁰

The threat of nuclear war during the Cold War conflict incentivized the United States to increase its national productivity capabilities to compete with the USSR. Historical precedent and the current geopolitical (and socioeconomic) climate illustrate that the primary threat facing our nation—and the world population—stems from a global pandemic. As each new

⁸ *Id.*

⁹ *Youngstown Sheet & Tube Co. v. Sawyer*, 343 U.S. 579 (1952).

¹⁰ *Outbreak Readiness and Business Impact: Protecting Lives and Livelihoods Across the Global Economy*, WORLD ECON. FOR. 5, 6 (2019), http://www3.weforum.org/docs/WEF%20HGHI_Outbreak_Readiness_Business_Impact.pdf [hereinafter *Outbreak Readiness and Business Impact*].

epidemic hits the population, our ability as a nation to support and protect not only our own citizens, but those around the world from a global pandemic, must shift to one of “total war” against disease rather than against other nations.¹¹

“On the 100th anniversary of the 1918 influenza pandemic, it is tempting to believe the world has seen the worst epidemics.”¹² A mere two years later, another deadly pandemic has swept the world. This virus, Severe Acute Respiratory Syndrome coronavirus 2 (SARS-CoV-2), commonly referred to as “COVID-19,” has infected and killed people belonging to every age group, wealth class, race, ethnicity, and geographic location. The Centers for Disease Control and Prevention (CDC) has established January 21, 2020, as the beginning of the outbreak. As of March 18th, 2021, there have been a total of 29,431,658 cases and 535,217 deaths caused by COVID-19 and related complications in the United States.¹³ In the seven days prior to March 18th, there were 376,410 confirmed new cases in the United States.¹⁴ By the same date, there had been over 122 million cases and almost 2.7 million deaths worldwide.¹⁵ COVID-19 has been difficult to contain even with precautions (e.g., closing borders, quarantining the sick or symptomatic, etc.) because of the high number of contagious, asymptomatic individuals.¹⁶ Prior to the development of several vaccines, the spread of COVID-19 was hampered by social distancing, use of personal protective equipment (PPE), and frequent testing.¹⁷ While nations have enforced general guidelines to implement all three of these aforementioned measures (*i.e.*, social distancing, the use of PPE, and frequent testing), the United States has been obstructed by a lack of supplies,¹⁸ particularly affordable and effective PPE. This is especially true for healthcare providers. Unfortunately, 3M, which is the current patent owner of the N95 respirator mask, can only produce a limited number of masks. 3M recently announced their *intended* response to the vastly-increased need incurred by the

¹¹ ERICH LUDENDORFF, *DER TOTALE KRIEG* (1935) (translated to “The Total War”) (expanding on the idea that war in the modern era requires total mobilization of manpower and resources. Global pandemics infect all aspects of life—like the German army in WWI and WWII, by attacking civilian-associated resources and infrastructure. The United States must also adapt appropriately in response.).

¹² *Outbreak Readiness and Business Impact*, *supra* note 10.

¹³ *United States COVID-19 Cases, Deaths, and Laboratory Testing (NAATs) by State, Territory, and Jurisdiction*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://covid.cdc.gov/covid-data-tracker/#cases_casesinlast7days (last visited Mar. 18, 2021) [hereinafter CTRS. FOR DISEASE CONTROL & PREVENTION].

¹⁴ *Id.*

¹⁵ *COVID-19 Coronavirus Pandemic*, WORLDOMETER, <https://www.worldometers.info/coronavirus/> (last visited Feb. 14, 2021).

¹⁶ Katie Kerwin McCrimmon, *The Truth About COVID-19 and Asymptomatic Spread: It’s Common, so Wear a Mask and Avoid Large Gatherings*, UCHEALTH (Nov. 5, 2020), <https://www.uchealth.org/today/the-truth-about-asymptomatic-spread-of-covid-19/> (a recent study found that nearly 40% of children who tested positive for COVID-19 were asymptomatic. People of all ages can be asymptomatic and can still spread the virus to others.).

¹⁷ *Id.*

¹⁸ *Medical Device Shortages During the COVID-19 Public Health Emergency*, FOOD & DRUG ADMIN. (Mar. 19, 2021), <https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/medical-device-shortages-during-covid-19-public-health-emergency>.

pandemic, which includes plants running on a twenty-four hour per day, seven day per week basis.¹⁹ This intended response would triple the production rate to over 95 million respirators per month in the United States.²⁰ It would maximize production of other solutions in response to COVID-19, including biopharma filtration systems, hand sanitizers, and disinfectants.²¹ The increased production of these other COVID-19 response tools would have saved—and could still save—a significant number of lives.²² This note advocates that the United States may achieve efficient and rapid production through compulsory licensing, therefore allowing more than one company to produce the PPE. Mass production of this kind is necessary to combat the pandemic more successfully when it is a particular good or material that is not being freely produced on the market in sufficient supply.

N95 respirators and surgical masks are examples of personal protective equipment that are used to protect the wearer from airborne particles and liquid contaminating the face. The CDC and Prevention National Institute for Occupational Safety and Health (NIOSH) and the Occupational Safety and Health Administration (OSHA) regulate N95 respirators.²³

While PPE alone does not prevent airborne transmission, N95 respirators are labeled as “critical supplies” used by essential workers.²⁴ To produce N95 respirators at a rate necessary for an effective pandemic response, compulsory licensing initiated by the DPA is required.

Since the declaration of COVID-19 as a global pandemic, the threat facing individuals in the United States has become even more complex as new variants have arisen. There are more noteworthy strains of COVID-19 originating from mutations developed or accumulated as the disease passed through the populations of South Africa and the United Kingdom.²⁵ The

¹⁹ *Helping the World Respond to COVID-19*, 3M, https://www.3m.com/3M/en_US/company-us/coronavirus/ (last visited Sept. 11, 2021) [hereinafter 3M].

²⁰ *Id.*

²¹ *Id.*

²² Peter Coy, *Mandatory Mask Use Could Have Saved 40,000 Lives, Study Says*, BLOOMBERG BUSINESSWEEK (July 2020, 6:00 AM), <https://www.bloomberg.com/news/articles/2020-07-16/mandatory-mask-use-could-have-saved-40-000-lives-study-says> (“Using statistical analysis, [a new study] concludes that 40,000 lives would have been saved in two months if a national mask mandate for employees of public-facing businesses had gone into effect on April 1 [2020] and had been strictly obeyed.”).

²³ *N95 Respirators, Surgical Masks, and Face Masks*, FOOD & DRUG ADMIN. (Aug. 20, 2020), <https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/n95-respirators-surgical-masks-and-face-masks>.

²⁴ *Id.* (essential workers include—but are not limited to—healthcare workers, medical doctors, nurses, and first responders.).

²⁵ See Houriiyah Tegally et al., *Sixteen Novel Lineages of SARS-CoV-2 in South Africa*, 27 NATURE MED. 440 (2021); see also, Kathy Katella, *Omicron, Delta, Alpha, and More: What to Know About the*

World Health Organization stated that, as of January 2, 2022, “[sixty] countries across all six WHO regions have reported either imported cases or community transmission of [the United Kingdom] variant”²⁶ The fear is that as infection rates increase across countries, particularly concerning variants will continue to arise and may make the vaccinations less impactful. “These mutations could render the current [COVID]-19 vaccines less effective. Or they could mean the virus eventually ‘escapes’ them all together. That’s why doctors, virologists, and other health researchers are calling on officials to ‘vaccinate 24/7 like it’s an emergency.’”²⁷ As the omicron variant currently makes its way through the United States three full years after the declaration of a global pandemic, the need for measures to be taken has not lessened.

This note’s proposed expansion to the DPA, which would create additional executive powers to compel, or if need be, force, private companies to share proprietary information has been contested in front of the courts before. Relevant analysis on the extent of the executive branch wielding this power begins with the precedent United States Supreme Court case of *Youngstown Sheet & Tube Co. v. Sawyer*,²⁸ and a discussion of the opinions’ themes.

I. YOUNGSTOWN

By the late 1940s, labor organizations had become a powerful force in America, and worker strikes caused large-scale fear in both the executive and legislative branches of the government.²⁹ A prime example of the power of labor organizations during that time emerged in the Supreme Court case *Youngstown Sheet & Tube Co. v. Sawyer*.³⁰ *Youngstown* stems from a dispute in the late 1950s between steel mill owners and their employees concerning their collective bargaining agreement.³¹ President Truman believed that if a strike came to pass, it would threaten steel supplies during the Korean War and compromise national defense.³² Facing potential steel

Coronavirus Variants, YALE MED., <https://www.yalemedicine.org/news/covid-19-variants-of-concern-omicron> (last visited Dec. 20, 2021).

²⁶ *COVID-19 Weekly Epidemiological Update*, WORLD HEALTH ORG., <https://www.who.int/publications/m/item/weekly-epidemiological-update-on-covid-19---6-january-2022> (data received by WHO from national authorities, as of January 17, 2021, 10:00 AM) (last visited Feb. 7, 2021).

²⁷ Julia Belluz & Umair Irfan, *How the New Covid-19 Variants Could Pose a Threat to Vaccination*, VOX MEDIA (Jan. 20, 2021, 9:15 AM), <https://www.vox.com/22213033/covid-19-mutation-variant-vaccine-uk-south-africa>.

²⁸ 343 U.S. 579 (1952).

²⁹ Cross Currents, *U.S. Labor Unions in the 1940s*, CULCON (2003), <http://www.crosscurrents.hawaii.edu/content.aspx?lang=eng&site=us&theme=work&subtheme=UNION&unit=USWORK010#>.

³⁰ *Youngstown Sheet & Tube Co. v. Sawyer*, 343 U.S. 579 (1952).

³¹ *Id.* at 582.

³² *Id.* at 583 (“The President [believed] that the proposed work stoppage would immediately jeopardize our national defense and that governmental seizure of the steel mills was necessary in order to assure the continued availability of steel.”).

shortages, a necessary component in weapons and war materials,³³ President Truman issued Executive Order 10340, directing the Secretary of Commerce Sawyer (the named defendant in *Youngstown*) to take control of and continue operating most of the nation's steel mills to prevent the strike.³⁴ This action was contested by the Youngstown Sheet & Tube Co. (the named plaintiff) and other steel mill operators.³⁵ This legal challenge climbed through the courts before the Supreme Court granted certiorari.³⁶ The steel mills argued that the President, under his constitutional executive powers, did not have the authority to issue the lawmaking order that directed the Secretary of Commerce to take possession of and operate the nation's steel mills without *Congressional or Constitutional authority to act*.³⁷ The Court was divided six to three, with the majority opinion written by Justice Black.³⁸ The Court came down in favor of the steel mills, and stated that the President's seizure order could not stand without the lawmaking power of Congress.³⁹ War powers granted to the Executive by the Constitution did not apply because there had been no declaration of war.⁴⁰

The three concurrences—by justices Frankfurter, Jackson, and Clark—focused on one central point: Congress's silence on the issue of Executive power to seize industries when there is threat of strike.⁴¹ Where Congress has explicitly or impliedly granted power to the Executive, the President may rely upon their own powers and those delegated by Congress; however, where Congress is silent, the President may only rely on his own independent powers.⁴² These justices all stated that there is a proverbial “grey area” where Congressional and Presidential powers can collide in the absence of clear Congressional legislation or constitutional delegation to the executive branch.⁴³ When “the President takes measures incompatible with the express or implied will of Congress, his power is at its lowest ebb . . . [The Supreme Court] can sustain exclusive presidential control in such case only by disabling the Congress from acting upon the subject.”⁴⁴ If Congress intended to intervene or offer a stance, they would have done so; therefore,

³³ *Id.* (“The President, a few hours before the strike was to begin, issued Executive Order 10340.”).

³⁴ *Id.*; *see also id.* at 590 (“Steel is an indispensable component of substantially all of such weapons and materials.”).

³⁵ *Id.* at 583.

³⁶ *Id.* at 583–84.

³⁷ *Id.* at 588.

³⁸ *Id.* at 582.

³⁹ *Id.* at 589.

⁴⁰ *Id.* at 642 (Jackson, J., concurring).

⁴¹ *See id.* at 602–03 (Frankfurter, J., concurring); *Cf. id.* at 635–40 (Jackson, J., concurring); *Cf. id.* at 662 (Clark, J., concurring).

⁴² *Id.* at 635–38 (Jackson, J., concurring).

⁴³ *Id.* at 597 (Frankfurter, J. concurring) (citations omitted) (the great ordinances of the Constitution do not establish and divide fields of black and white); *see also id.* at 637 (Jackson, J. concurring); *see also id.* at 662 (Clark, J. concurring) (stating in a slightly different manner that where Congressional procedures are lacking, “the President’s independent power to act depends upon the gravity of the situation confronting the nation.”).

⁴⁴ *Id.* at 637–38 (Jackson, J., concurring).

an important aspect of this note's proposal is the idea that editing the DPA to grant the President a power to act must come through *legislative* action.

The reason that Congressional ratification is important to this note's proposal is also based upon a secondary argument in *Youngstown*. The second argument is in Justice Douglas' concurring opinion:⁴⁵ although the federal government could seize the steel mills, it could only do so through the power of eminent domain and with subsequent Congressional ratification of the seizure.⁴⁶ The power to seize private property rests squarely with Congress because only Congress could appropriate money to compensate owners for a seizure of property.⁴⁷ "The President might seize and the Congress by subsequent action might ratify the seizure . . .,"⁴⁸ but no seizure would be lawful under the precedent of *Youngstown* until after such ratification occurred and payment is accounted for by Congress; complying with the theory of checks and balances.⁴⁹ Due to the essential nature of compensation, this note's proposed language for the DPA makes certain that companies complying with compulsory licenses would be compensated with due and just royalties for their products' use. Compulsory licenses "are authorizations given to a third-party by the Government to make, use, or sell a particular product or use a particular process which has been patented, without the need of the permission of the patent owner."⁵⁰

Justice Vinson wrote the only dissent in *Youngstown* joined by justices Reed and Minton.⁵¹ He argued that the President acted in a necessary way to prevent a crisis of national defense resulting from a likely steel shortage that would be brought on by a strike.⁵² Vinson argued that the President is uniquely qualified to implement this program, as he is authorized to exert *the power of the United States* when he finds it necessary for the protection of the United States.⁵³ The President's power and independence are fully within the powers conferred to the executive branch by the Constitution,⁵⁴ as the Framers intended the executive branch to be robust enough to serve as an effective check and balance to the other branches of government.⁵⁵ Similar to Justice Vinson's dissent,⁵⁶ this note argues that the Executive is

⁴⁵ Cf. at 629–34 (Douglas, J., concurring).

⁴⁶ *Id.* at 631.

⁴⁷ *Id.*

⁴⁸ *Id.* at 631.

⁴⁹ *Id.* at 631–32.

⁵⁰ Rebecca Furtado, *What Is the Concept of 'Compulsory License' Under the Patents Act, 1970*, IPLEADERS (Sept. 26, 2016), <https://blog.ipleaders.in/concept-compulsory-license-patents-act-1970/>.

⁵¹ *Youngstown*, 343 U.S. at 667–710 (Vinson, J. dissenting).

⁵² *Id.* at 667.

⁵³ *Id.* at 691.

⁵⁴ *Id.* at 681–82.

⁵⁵ *Id.* at 682 (the Framers created a system in which no autocrat would be capable of arrogating power onto himself at any time. Nor did the Framers create an automaton unable to exercise the powers of the Government at a time when the survival of the Republic itself may be at stake.).

⁵⁶ *Id.* at 703–04 (citations omitted) (while emergency does not create power, emergency may furnish the occasion for the exercise of power. The Framers knew that there is real danger in executive weakness.).

the only branch capable of quick and decisive action when a national emergency strikes; therefore, additional language is needed in the DPA.

Youngstown applies to the proposal at hand because it is a demonstration that the President's seizure will likely only pass through a judicial review if it is first approved by the legislature. This approval can come in the form of passing legislation or through the legislature's approval to pay for eminent domain costs or fair compensation to property owners. Such a seizure may have been unconstitutional at the time; however, the Court's holding identified that the seizure managed to prevent a steel shortage during wartime. Today, as during *Youngstown*, the President could utilize the DPA, but would be hamstrung by the law's inability to be enacted quickly and constitutionally outside of cases following a declaration of war. The Executive could respond to national crises faster and more efficiently if it could license patent ownership to contractors to increase production of needed goods. Currently, an issue with being dependent on an Executive Order—like in *Youngstown*—is that the Order could be stayed by the judicial branch. This issue could result in a costly loss of time while a deadly virus spreads unfettered. If congress enacts legislation, there does not need to be an application of *Youngstown* because the legislation would solve the *Youngstown* majority's negative treatment of President Truman's Executive Order. In other words, Congressional legislation expanding the DPA would remove the majority's argument in *Youngstown* by preauthorizing the type of action taken by President Truman, removing the need for later ratification, and therefore making the executive branch more efficient when crisis arise.

Legislation must be adjusted to fit new challenges. The Founding Fathers did not have to react to rapidly spreading viruses.⁵⁷ There was no expectation of the government to protect the people from germs, enact national healthcare standards, or to protect emergency responders from falling ill. Now that there is such an expectation placed on the government,⁵⁸ that standard can only be achieved if we grant the Executive that authority.

Youngstown is also distinguishable from the current crisis in that a steel shortage, while hypothetically catastrophic to the war effort, did not materialize to the point of necessitating intervention. President Truman was acting in a preventative manner.⁵⁹ Unlike the hypothetical steel shortage during the Truman administration, there is a documented and realized

⁵⁷ Disease has affected populations on large scales before, including during the time of the Founding Fathers. Nonetheless, the modern era of efficient travel, mass migration, and population growth has proportionally increased the degree of diseases affect and thus there is a growing need for government intervention.

⁵⁸ Mary Gerisch, *Health Care as a Human Right*, AM. BAR ASS'N (“[T]he UN’s Universal Declaration of Human Rights (UDHR) ... codified our human rights, including, at Article 25, the essential right to health. The United States, together with all other nations of the UN, adopted these international standards.”), https://www.americanbar.org/groups/crsj/publications/human_rights_magazine_home/the-state-of-healthcare-in-the-united-states/health-care-as-a-human-right/ (last visited Feb. 21, 2021).

⁵⁹ *Youngstown*, 343 U.S. at 709 (Vinson, J. dissenting) (the President informed Congress that even a temporary Government operation of plaintiffs’ properties was ... necessary to prevent immediate paralysis of the mobilization program.).

shortage of PPE today.⁶⁰ Using the logic of the *Youngstown* Court, compulsory licensing of patented intellectual property and the seizure of factories that produce PPE would be justified; however, new Congressional legislation to remove the “silence” issue⁶¹ is needed if this executive action is to survive a constitutional challenge.

II. CURRENT LANGUAGE OF THE DPA AND OTHER EXECUTIVE POWERS

A. *Defense Production Act*

The DPA confers powers upon the executive branch of the United States government to influence, shape, or control domestic industries in the interest of national defense.⁶² While the DPA was passed during the Korean War, the justification stems from the War Powers Acts of the second World War.⁶³ It was reauthorized, most recently, in the John S. McCain National Defense Authorization Act for Fiscal Year 2019.⁶⁴ That Act extended the current powers through September 30, 2025, at which point all DPA authorities will cease unless reauthorized by Congress.⁶⁵

The DPA has expanded since its original enactment. It now provides that, “the authorities may also be used to enhance and support domestic preparedness, response, and recovery from natural hazards, terrorist attacks, and other national emergencies.”⁶⁶ Currently, the statute defines “national defense” as:

[P]rograms for military and energy production or construction, military or critical infrastructure assistance to any foreign nation, homeland security, stockpiling, space, and any directly related activity. Such term includes emergency preparedness activities conducted pursuant to title VI of The Robert T. Stafford Disaster Relief and Emergency Assistance Act [42 U.S.C. § 5195 et seq.]⁶⁷ and critical infrastructure protection and restoration.⁶⁸

⁶⁰ Tim Darnell, *U.S. Faces Another Shortage of PPE, Including Masks, as Virus Surges*, ATLANTA J. - CONST. (Nov. 6, 2020), <https://www.ajc.com/news/nation-world/us-faces-another-shortage-of-ppe-including-masks-as-virus-surges/GOZYMR3GTRAWTMYLBZCEVCLNAU/>.

⁶¹ *Youngstown*, 343 U.S. at 589.

⁶² Defense Production Act of 1950, Pub. L. No. 81-774, 64 Stat. 798 (codified as amended at 50 U.S.C. §§ 4501 et seq.) (current through P.L. 116-193).

⁶³ CECIRE & PETERS, *supra* note 7.

⁶⁴ John S. McCain National Defense Authorization Act (“NDAA”) for Fiscal Year 2019, Pub. L. No. 115-232, 132 Stat. 1636 (2018).

⁶⁵ *Id.*

⁶⁶ CECIRE & PETERS, *supra* note 7.

⁶⁷ See 42 U.S.C. § 5195(a)(3) (Title VI of the Stafford Act is the location of a further definition of “emergency preparedness” activities. “. . . means all those activities and measures designed or undertaken to prepare for or minimize the effects of a hazard upon the civilian population, to deal with the immediate emergency conditions which would be created by the hazard, and to effectuate emergency repairs to, or the emergency restoration of, vital utilities and facilities destroyed or damaged by the hazard.”).

⁶⁸ *Defense Production Act*, FED. EMERGENCY MGMT. AGENCY (July 24, 2020), <https://www.fema.gov/disaster/defense-production-act-dpa-definitions>.

The other categories of qualifying circumstances, including national emergencies, are not clearly defined by the statute.

There are three remaining Titles, of the original seven, in the DPA that Congress has repeatedly reauthorized.⁶⁹ Title I details priorities and allocations that allow the President to require persons to concentrate on and accept contracts for materials and services in the name of national defense.⁷⁰ Title III allows the President to incentivize domestic industries to increase production and supplies of needed goods through loans, loan guarantees, and direct purchases.⁷¹ It also includes the power to procure and install federal equipment into privately-held factories.⁷² Title VII is mostly definitions and includes a list of powers and limitations for the Executive and the Act in general.⁷³ Examples include executive authority to direct special preference to small businesses, to order assessments of the current state of the domestic industry, and others.⁷⁴

The executive power to delegate priorities and allocations is the bedrock of the Presidential power to form and accept contracts for materials and services in the name of national defense.⁷⁵ Despite this fact, Title I has (in part) been delegated to particular cabinet secretaries. The President acts by delegating authority to various departments within the executive branch. The purpose of this delegation of power is to spread out the administrative burden of soliciting, reviewing, and overseeing the contracts. For example, the Secretary of Health and Human Services has been assigned a set of priorities and allocation authorities for “health resources” under Title I of the DPA.⁷⁶ These “health resources,” would include drugs, biological products, medical devices, materials, and other services and equipment required to diagnose, mitigate, prevent impairment, improve, treat, cure, or restore the physical or mental health conditions of the population.⁷⁷ The N95 mask and its patent would certainly qualify as either a medical device or health supply used to mitigate or prevent a health condition. As such, while the President would be responsible for seizing the patent under the proposed DPA powers, it would likely be the responsibility of the Secretary of Health and Human Services to grant that patent to the appropriate businesses that could produce the N95. It would also be the responsibility of the Secretary of Health and Human Services to allocate where the PPE would be

⁶⁹ See Defense Production Act of 1950, Pub. L. No. 81-774, 64 Stat. 798 (codified as amended at 50 U.S.C. §§ 4501 et seq.) (current through P.L. 115-232, enacted Aug. 13, 2018); see also CONG. RSCH. SERV., *Defense Production Act: Purpose and Scope* (May 14, 2009), <https://sgp.fas.org/crs/natsec/RS20587.pdf>.

⁷⁰ 50 U.S.C. §§ 4511–4518.

⁷¹ 50 U.S.C. §§ 4531–4534.

⁷² 50 U.S.C. § 4533(e).

⁷³ 50 U.S.C. §§ 4552–4568.

⁷⁴ 50 U.S.C. § 4551(e).

⁷⁵ 50 U.S.C. § 4511(a).

⁷⁶ See Exec. Order No. 13,603, 77 Fed. Reg. 16,651 (Mar. 22, 2012).

⁷⁷ *Id.* at § 201(3).

distributed (e.g., to market, to specifically assigned hospitals, or to other necessary businesses).

B. Executive Orders to Combat SARS-CoV-2

On March 13, 2020, President Trump issued Proclamation 9994.⁷⁸ The proclamation declared a national emergency concerning the novel COVID-19 pandemic and suspended entry of persons into the country who would pose a risk of transmitting the virus.⁷⁹ This was the first executive action that recognized the threat to the national healthcare system and the citizens at risk of COVID-19-related health-complications; however, this action did not occur until fifty-two days after what the CDC classifies as the inaugural day of the COVID-19 outbreak on January 21, 2020.⁸⁰

It was not until March 27th, 2020 that President Trump made mention of the DPA.⁸¹ To respond to the spread of COVID-19, Executive Order 13909 delegated the powers given under the DPA to prioritize and allocate health and medical resources to the Secretary of Health and Human Services.⁸² This Executive Order was insufficient and a simple lack of production of needed materials and resources quickly became an issue.⁸³ The Executive Order was largely limited to assessment and controlling distribution of materials because of the material failings of the DPA. 3M is one of the largest producers of PPE, yet it is the only N95 respirator producer in the United States.⁸⁴ 3M produces about 35 million N95 masks per month and exports large quantities from that supply to Canada and Latin America.⁸⁵ The exportation of needed materials lowers the availability to satisfy the domestic demand; to stop the exportation would require government intervention. An expansion of production to other entities—rather than relying on one entity—can increase supply without relying on nationalization or policing corporations to first serve domestic needs. This is another way that an expansion of the DPA could prevent corporate discontent.

President Trump released a second Executive Order on March 23, 2020.⁸⁶ Executive Order 13910 was intended to prevent the hoarding of health and medical resources by private citizens to better distribute resources

⁷⁸ Proclamation No. 9994, 85 Fed. Reg. 15,337 (Mar. 13, 2020).

⁷⁹ *Id.*

⁸⁰ *CDC's Response*, CTRS. FOR DISEASE CONTROL & PREVENTION (Sept. 11, 2020), <https://www.cdc.gov/coronavirus/2019-ncov/cdcresponse/index.html>.

⁸¹ Exec. Order No. 13,909, 85 Fed. Reg. 16,227 (Mar. 18, 2020).

⁸² *Id.*

⁸³ Darnell, *supra* note 60.

⁸⁴ Morgan Watkins, *Kentucky Gov. Andy Beshear Calls on 3M to Release Patent for N95 Respirator Amid Pandemic*, LOUISVILLE COURIER J. (Apr. 3, 2020, 12:01 PM), <https://www.courier-journal.com/story/news/2020/04/03/beshear-calls-3-m-release-patent-n-95-respirator-amid-pandemic/5112729002/>.

⁸⁵ *Id.*

⁸⁶ Exec. Order No. 13,910, 85 Fed. Reg. 17,001 (Mar. 23, 2020).

in response to COVID-19.⁸⁷ This Order also delegated the presidential “authority under the Act to implement any restrictions on hoarding, including [the President’s] authority under section 705 of the Act (50 U.S.C. 4555) to gather information, such as information about how supplies of such resources are distributed throughout the Nation” to the Secretary of Health and Human Services.⁸⁸ Similar to Executive Order 13911, Executive Order 13910 failed to meet the need for N95s during the global pandemic. Neither of these Executive Orders directed the domestic industry to produce N95s—or any PPE. They merely permit the Secretary to assess the PPE stockpiles and to determine prioritization for allocation. Even if all the N95s produced by 3M in the United States were retained and distributed solely to domestic healthcare workers, there would not even be enough for every healthcare worker to have two masks per month.⁸⁹ N95s are reusable to an extent,⁹⁰ but with approximately 18 million healthcare workers in the United States, we need to increase production of N95 masks rapidly.⁹¹

President Trump signed several other Executive Orders during his presidency in relation to COVID-19. On April 28th, 2020, Executive Order 13917 delegated authority to the Secretary of Agriculture to protect and prioritize food supplies by nationalizing the meat and poultry safe operations guidelines.⁹² On May 14th, 2020, Executive Order 13922 delegated authority to the Chief Executive Officer of the United States International Development Finance Corporation (DFC) to create, maintain, protect, expand, and restore the domestic industrial base capabilities.⁹³ Along with others, President Trump also signed Executive Orders to prevent or at least slow evictions,⁹⁴ and one ensuring essential medicines, medical

⁸⁷ *Id.*

⁸⁸ *Id.*

⁸⁹ Larry Levitt et al., *Estimates of the Initial Priority Population for COVID-19 Vaccination by State*, KAISER FAM. FOUND. (Dec. 10, 2020), <https://www.kff.org/coronavirus-covid-19/issue-brief/estimates-of-the-initial-priority-population-for-covid-19-vaccination-by-state/> (nationwide, there are 19.7 million adults working in healthcare settings, of which roughly 15.5 million are estimated to have direct patient contact) (with 3M producing an estimated 35 million N95 masks per month, and around 15.5 million healthcare workers the math is simply 35 divided by 15.5 equaling roughly 2 masks per healthcare worker.).

⁹⁰ Paulina Firozi & Allyson Chiu, *How often can you safely reuse your KN95 or N95 mask?* THE WASH. POST (Jan. 14, 2022, 2:28 PM), <https://www.washingtonpost.com/health/2022/01/13/KN95-n95-mask-reuse-omicron/> (stating that there are no hard and fast rules but that when there are visible signs of soiling the mask is no longer reusable, with normal use you can wear a mask for a few hours a day for four to five days.).

⁹¹ THE NAT’L INST. FOR OCCUPATIONAL SAFETY & HEALTH (NIOSH), *Healthcare Workers*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/niosh/topics/healthcare/default.html> (last visited Nov. 22, 2020).

⁹² Exec. Order No. 13,917, 85 Fed. Reg. 26,313 (Apr. 28, 2020) (this delegation was in part due to outbreaks of COVID-19 among workers at some processing facilities that led to a reduction in some of those facilities’ production capacity, the Secretary was assigned and given power to circumvent State(s) authority to recommend closure of these plants for safety reasons to continue functioning of the national meat and poultry supply chain.).

⁹³ Exec. Order No. 13,922, 85 Fed. Reg. 30,583 (May 14, 2020).

⁹⁴ Exec. Order No. 13,945, 85 Fed. Reg. 49,935 (Aug. 8, 2020) (the CDC had observed that homelessness poses multiple challenges that can exacerbate and amplify the spread of COVID-19).

countermeasures, and critical inputs are made in the United States.⁹⁵ President Biden likewise attempted to tackle the pandemic with a series of Executive Orders,⁹⁶ but neither of the Presidents addressed the fact that 3M was not producing enough N95 masks in order to protect domestic healthcare workers.

The severe need for N95 respirators was exasperated by a depletion of the Strategic National Stockpile (SNS).⁹⁷ An investigative documentary revealed that—due to unheeded warnings and congressional failure—the SNS warehouses that were supposed to contain necessary PPE were never refilled after being depleted during the Obama administration’s handling of the 2009 H1N1 pandemic.⁹⁸ Greg Burel, the former head of the SNS, stated that during the H1N1 pandemic, the SNS “showed [that they] could get that material out rapidly, and it could be made available.”⁹⁹ Executive Orders regarding PPE distribution during a pandemic cannot be impactful without plentiful stockpiles for the Secretary of Health and Human Services to distribute. The existence of the SNS allows the executive branch or congress to distribute resources as needed without having to purchase or seize materials from distributors or manufacturers. It in part shortens the process because the materials are ready to be distributed as needed. Without supplies and materials in the SNS, the executive branch during COVID has been left attempting to find supplies that may have already been purchased on the market by other parties including private citizens, other corporations, or even foreign nations.

The demand for PPE during a pandemic—where masks are needed in massive quantities over an extended period—will never be matched by the executive branch merely preventing hoarding of resources. To meet the demand of a pandemic, production must be increased; moreover, augmented production needs to be directed under the President’s current DPA Title I power so that supplies can be prioritized for healthcare facilities, emergency first responders, and other essential workers. “In Italy, health care workers experienced high rates of infection and death partly because of inadequate access to PPE. And recent estimates here in the United States suggest that we will need far more respirators and surgical masks than are currently

⁹⁵ Exec. Order No. 13,944, 85 Fed. Reg. 49,934 (Aug. 6, 2020) (policy was based on a desire to have domestic supply chains capable of meeting national security requirements for responding to threats arising from public health emergencies such as COVID-19 and to reduce our reliance on foreign imports for essential medicines, medical countermeasures, and critical inputs.).

⁹⁶ See Federal Register, *2020 Donald Trump Executive Orders*, NAT’L ARCHIVES, <https://www.federalregister.gov/presidential-documents/executive-orders/donald-trump/2020> (last visited Mar. 26, 2021); see also Federal Register, *2021 Joe Biden Executive Orders*, NAT’L ARCHIVES, <https://www.federalregister.gov/presidential-documents/executive-orders/joe-biden/2021> (last visited Mar. 26, 2021).

⁹⁷ Patrice Taddonio, *Depleted National Stockpile Contributed to COVID PPE Shortage: ‘You Can’t Be Prepared If You’re Not Funded to Be Prepared’*, FRONTLINE (Oct. 6, 2020), <https://www.pbs.org/wgbh/frontline/article/depleted-national-stockpile-contributed-to-covid-ppe-shortage/>.

⁹⁸ *Id.*

⁹⁹ *Id.*

available.”¹⁰⁰ Before the COVID-19 pandemic, China produced roughly half of the world’s face masks.¹⁰¹ Now China is largely withholding exports of its own masks and PPE due to domestic need for its own population and healthcare workers.¹⁰² Without increased domestic production, the United States will fail to meet its own needs.

III. IMPEDIMENTS TO LEGISLATIVE ACTION

A. *Bayh-Dole Act as a Form of Patent Seizure*

The proposed added powers to the DPA are not novel in all respects. In some cases, the executive powers of compulsory licensing and seizure of proprietary information or technology are already allowable. Under the Bayh-Dole Act, the federal government retains certain rights to inventions, patents, and proprietary information produced with its *financial assistance*.¹⁰³ The Bayh-Dole Act may have allowed the government to obtain several rights in federally funded subject inventions, but it did not displace the norm that rights in an invention belonged to the inventor. This has been upheld by courts, and the Act is interpreted in a manner that “contractors may ‘elect to retain title to any subject invention.’”¹⁰⁴ The Bayh-Dole Act was passed by Congress with the intention of leveraging the patent system to promote the utilization of inventions that arise from federally funded research and development;¹⁰⁵ however, the federal government could take action as “necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees.”¹⁰⁶ In other words, if 3M or any other company had received federal funding for the development of its N95 masks and the company failed to meet the health needs of the nation—specifically in the context of the COVID-19 pandemic—the patent could have been seized and distributed by the government. While the Bayh-Dole federal funding is useful for small businesses, universities, and other nonprofit institutions, private companies frequently pay for their own research and development and do not qualify for this kind of “patent taking.”

¹⁰⁰ Megan Ranney et al., *Critical Supply Shortages, The Need for Ventilators and Personal Protective Equipment During the Covid-19 Pandemic*, 382 NEW ENG. J. MED. e41(1), e4(1) (Apr. 30, 2020).

¹⁰¹ *Id.*

¹⁰² *Id.*

¹⁰³ JOHN R. THOMAS, CONG. RSCH. SERV., R44597, MARCH-IN RIGHTS UNDER THE BAYH-DOLE ACT (Aug. 22, 2016), <https://sgp.fas.org/crs/misc/R44597.pdf>.

¹⁰⁴ Bd. of Tr. of the Leland Stanford Junior Univ. v. Roche Molecular Sys., 563 U.S. 776, 777, 786–87 (2011).

¹⁰⁵ *Id.* at 782.

¹⁰⁶ March-in Rights, 35 U.S.C. § 203(a)(2) (2011).

B. Compulsory Licensing of Federal Contract Holders

Compulsory licensing is a growing form of intellectual property and capital growth in many countries.¹⁰⁷ The Indian Patents Act of 1970 and the Trade-Related Aspects of Intellectual Property Rights (TRIPS) establish the provisions and rights of compulsory licenses.¹⁰⁸ “Such compulsory licenses are commonly used by satellite television providers, cable providers, webcasters, and music companies . . . allowing them to distribute and utilize content in an efficient and legal manner.”¹⁰⁹ These licenses are used every day to increase the number of companies producing generic medicines which in turn increases supply and lowers costs to patients around the world.

Producing any form of patentable technology or process can be expensive. A study done by the Tufts University Center for the Study of Drug Development (CSDD) estimated the cost of introducing a new drug to be approximately \$2.6 billion.¹¹⁰ Compulsory licensing can be used to overcome access and/or price barriers related to developing new technology. It can also serve as a disincentive for companies to pay reduced-but-substantial investing prices for new innovative technologies or medicines. This is because royalties for compulsory licenses are determined by the government and are often less than the private market could provide.¹¹¹

In 1995, the World Trade Organization (WTO) passed TRIPS to establish “minimum standards of protection and enforcement that each government adhere to for intellectual property held by [fellow member states].”¹¹² Under TRIPS, the “patent owner still has rights over the patent, including a right to be paid compensation for copies of the products made under the compulsory license.”¹¹³ A patent seizure under TRIPS, however, does not always require approval of the patent owner, particularly in cases of national emergencies or public noncommercial use.¹¹⁴ Under circumstances of national emergency, extreme urgency, or public non-

¹⁰⁷ Hilary Wong, *The Case for Compulsory Licensing During COVID-19*, 10 J. GLOB. HEALTH 1 (May 15, 2020), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7242884/> (approximately twenty countries have either issued or publicly entertained issuing a compulsory license for one or more pharmaceutical products since the founding of the WTO.).

¹⁰⁸ Furtado, *supra* note 50 (stating that compulsory licenses are authorizations given to a third-party by governments and can be found within provisions in both the Indian Patents Act of 1970 for United States authorization, and in the Trade-Related Aspects of Intellectual Property Rights Agreement for international authorization.)

¹⁰⁹ Richard Stim, *Copyright and Compulsory Licenses*, NOLO, <https://www.nolo.com/legal-encyclopedia/copyright-compulsory-license.html> (last visited Feb. 2, 2021).

¹¹⁰ William Alan Reinsch et al., *Compulsory Licensing: A Cure for Distributing the Cure?* CTR. FOR STRATEGIC & INT’L STUD. (May 8, 2020), <https://www.csis.org/analysis/compulsory-licensing-cure-distributing-cure>.

¹¹¹ WORLD HEALTH ORG., *Remuneration Guidelines for Non-Voluntary Use of a Patent on Medical Technologies*, HEALTH ECON. & DRUGS TCM SERIES NO. 18, 45 (2005) (stating that United States royalties for government use have ranged around 6%; however, royalties can and have been far lower in some important cases. There is substantial variation in terms for individual licenses which can range from less than 1% to more than 50%.), https://www.who.int/hiv/amds/WHOTCM2005.1_OMS.pdf.

¹¹² Reinsch et al., *supra* note 110.

¹¹³ *Compulsory licensing of pharmaceuticals and TRIPS*, WORLD TRADE ORG., https://www.wto.org/english/tratop_e/trips_e/public_health_fa_q_e.htm (last visited Jan. 20, 2022).

¹¹⁴ *Id.*

commercial use, the process of voluntarily licensing can usually be bypassed provided that the exception is limited to predominantly domestic use.¹¹⁵ The benefit to this form of intellectual property usage is that the government could provide N95s in one of three ways (all of which apply under compulsory licensing, with varying successes and drawbacks). First, third-party businesses and/or the federal government could attempt to negotiate a voluntary license from 3M with the understanding that the government could always force a compulsory license if negotiations break down. Second, the federal government could procure a contract that has a compulsory licensing clause as a condition. This change would allow other contractors to also produce the material and/or goods needed. The Department of Defense currently has a contract with 3M for N95 masks, but it is unknown if such a clause is within the contract or, if not, if it could be added.¹¹⁶ Third, the federal government could declare a national emergency and stipulate that companies could produce the N95s for purely public non-commercial use, clarifying that the government would purchase the N95's at a "fair price" to distribute them based on need.

IV. PROPOSED ADDITIONS

Title I of the DPA establishes that the President has the power to set national priorities as "he deems necessary or appropriate to promote the national defense... to allocate materials, services, and facilities in such manner, upon such conditions, and to such extent as he shall deem . . ."¹¹⁷ There are two parts to Title I separated by the primary functions of the title itself that provide the critical basis for this notes' proposed amendments. First, the priority performance authority ensures the timely availability of critical materials, equipment, and services produced by domestic industries in the interest of national defense.¹¹⁸ It also guarantees the ability of the President to receive those materials, equipment, and services through contracts without or before other competing interests.¹¹⁹ The prioritization authority in Title I of the DPA is a broader authority than in other statutes.¹²⁰

The second part involves the power of allocation given to the President to control the distribution of materials, services, and facilities.¹²¹ It is based upon these powers vested in the executive branch that I propose to add the executive power to issue compulsory licenses of intellectual property.¹²² The

¹¹⁵ Reinsch et al., *supra* note 110.

¹¹⁶ *DOD Awards \$126 Million Contract to 3M, Increasing Production of N95 Masks*, U.S. DEP'T OF DEF. (May 6, 2020), <https://www.defense.gov/Newsroom/Releases/Release/Article/2178152/dod-awards-126-million-contract-to-3m-increasing-production-of-n95-masks/> [hereinafter U.S. DEP'T OF DEF.].

¹¹⁷ Priority in Contracts and Orders, 50 U.S.C. § 4511(a) (2015).

¹¹⁸ *Id.*

¹¹⁹ *Id.*

¹²⁰ *See generally* Utilization of Industry, 50 U.S.C. § 3816 (2015).

¹²¹ 50 U.S.C. § 4511(a).

¹²² This is an authority already historically vested from Congressional legislation as a means of securing our national defense and handling national emergencies. *See* JOHN R. THOMAS, COMPULSORY

principle is already employed with “March-In Rights” existing under the Bayh-Dole Act;¹²³ however, it does not apply to the private businesses, such as 3M, which are not federally funded but produce most of our PPE.

I argue that my proposed language should be added directly to § 4517, titled “Strengthening Domestic Capability.” This section states that:

(a) **In general.** Utilizing the authority of title III of this Act [sections 4531 to 4534 of 50 U.S.C.] or any other provision of law, the President may provide appropriate incentives to develop, maintain, modernize, restore, and expand the productive capacities of domestic sources for critical components, critical technology items, materials and industrial resources essential for the execution of the national security strategy of the United States.¹²⁴

I propose a new subsection within § 4517, titled “(c) Compulsory Licensing of Critical Patents and or Proprietary Information”. It would contain the following:

- (1) **Maintenance of reliable sources of supply.** The President shall take appropriate actions to ensure that critical components, technologies, materials, products, and industrial resources are available from qualified and reliable sources to meet defense requirements during peacetime, graduated mobilization, and national emergency or conflict.
- (2) **Appropriate action.** For purposes of this subsection, “appropriate actions” may include but are not limited to:
 - (a) Compulsory licensing of private party and/or industry patents as needed to produce goods necessary to meet defense requirements during peacetime, graduated mobilization, and national emergency or conflict.
 - (b) Distribution of the intellectual property being licensed will be limited to qualified domestic private corporations and/or companies capable of producing the same critical components, technologies, materials, products, and industrial resources that the patent encompasses.
 - (i) The Government will establish a contract with any parties who will receive

LICENSING OF PATENTED INVENTIONS, CONG. RSCH. SERV., R43266 (Jan. 14, 2014), <https://crsreports.congress.gov/product/pdf/R/R43266> (stating that the Atomic Energy Act, Clean Air Act, and Plant Variety Protection Act already provide for compulsory licensing.).

¹²³ Pub. L. 96-517.

¹²⁴ Strengthening Domestic Capability, 50 U.S.C. § 4517(a) (1950) (enacted Aug. 13, 2018, current through Pub. L. 115-232).

the intellectual property for the purpose of limiting the usage to as-needed provisions and to prevent commercial distribution or sales.

(ii) The compensation for the compulsory licensing would be determined at a reasonable royalty of fair market value to be paid throughout the duration of time that the contract remains unfulfilled.

(c) Restricting patent disbursement and contract solicitation to domestic sources pursuant to:

(i) § 2304(b)(1)(B) or § 2304(c)(3) of Title 10, U.S.C.;

(ii) § 303(b)(1)(B) or § 303(c)(3) of the Federal Property and Administrative Services Act of 1949 [41 U.S.C.S. § 3303(a)(1)(C) or 3304(a)(3)]; or

(ii) other statutory authority.

(3) Refusal or willful prevention of compulsory licensing.

(a) If the needed intellectual property is not provided in a voluntary or transactional manner and there exists a national emergency, other circumstances of extreme urgency, or in cases of non-commercial use, the government retains the right to bypass any need or process for voluntary licensing in favor of compulsory licensing.

(b) If the intellectual property shall be withheld during the statuses of crisis for a malicious, willful, or wanton purpose, the sought-after proprietary information of critical components, technologies, materials, and industrial resources shall be made public to the global market and fair market compensation for the use of said intellectual property will be forfeit.

(4) Qualifying patents for licensing. For purposes of this subsection, patents and/or proprietary information is limited to:

(a) A United States patent owned or licensed by either a domestic or foreign corporation.

(i) To be held subject to the authority of Title III of this Act [§§ 4531 – 4524 of U.S.C.], a domestic or foreign corporation must be subject to congressional and executive powers.

- (ii) For a domestic or foreign corporation to be subject to congressional and executive powers, it must have either (1) filed its articles of incorporation or (2) be able to satisfy the minimum contacts analysis within the nation's borders.
- (b) The corporation or business must be given a reasonable time frame to comply with a compulsory licensing order prior to having its intellectual property seized.
 - (i) "Reasonable time" for purposes of this section is determined by executive discretion and the need to meet defense requirements during peacetime, graduated mobilization, and national emergency.
- (c) The patent must be a valid and qualifying patent under 35 U.S.C. 101, 102, 103, and 112.
 - (i) For purposes of the subsection "valid and qualifying" mean:
 - (1) The requirements for patentability include eligible subject matter, utility, novelty, non-obviousness, and enablement.

The purpose of this proposed language is to protect the public and corporations from having the executive branch seize (through compulsory licensing) any patent or intellectual property that can be reasonably justified as needed to meet defense requirements during peacetime, graduated mobilization, and national emergency. As previously established, cases of COVID-19 continue to climb, as does the death toll. Such a power could still save lives in the current national emergency brought on by the COVID-19 pandemic, especially given disease models based on new variant strain infections.¹²⁵

¹²⁵ THOMAS MCANDREW ET AL., META AND CONSENSUS FORECAST OF COVID-19 TARGETS (2021), https://github.com/computationalUncertaintyLab/aggStatModelsAndHumanJudgment_PUBL/raw/main/summaryreports/summaryReport01/MetaandConsensusForecastOfCOVID-19Targets.pdf (stating that a consensus of subject matter experts and trained forecasters predicted that 87% of United States samples sent for genomic sequencing in the first two weeks of February 2021 that have an S-gene dropout ... will be identified as the B.1.1.7 variant ... forecasters expect this to have important implications for decisions about non-pharmaceutical interventions and changes in the pace of vaccinations.).

VI. WHY TARGET 3M? WHY N95S SPECIFICALLY?

As of March 18, 2021, 535,217 people have died from COVID-19 within the United States.¹²⁶ Based on projected cases and infection rates, a study from the University of Washington's Institute for Health Metrics and Evaluation estimated that an additional 129,574 lives from September 22, 2020, through February 2021 could have been saved if 95% of the population wore face coverings and followed the recommended social restrictions.¹²⁷ There are simply *not enough* adequate PPE to protect the population. This problem is partially due to the convoluted combination of public perceptions regarding mask-wearing and early-on mixed messaging from public-health officials at the onset of the COVID-19 pandemic.¹²⁸ On February 29, 2020, the United States surgeon general, Dr. Jerome Adams, tweeted that masks do not offer any benefit to the average citizen, but concurrently stressed that "if healthcare providers can't get them to care for sick patients, it puts them and our communities at risk!"¹²⁹ The suggestion that healthcare providers are the only individuals that need PPE or other forms of virus protection is not widely supported;¹³⁰ however, it is important that they receive a steady and priority supply of more rigorous forms of PPE given their frequent and prolonged contact with infected individuals and their likelihood to spread the virus to others.

The Governor of Kentucky, Andy Beshear, called for 3M to release its patent for the N95 respirator on April 1, 2020, to help increase production to combat the needs presented by the pandemic.¹³¹ While 3M did increase production,¹³² the issue with a single company controlling a major PPE patent is that they often cannot rapidly expand their production to match an exponentially increased need. 3M has made statements that it intends to globally double its current capacity within twelve months of March 2020.¹³³ Increasing production takes time, however, time that can be saved by increasing the number of producers not just the capabilities of one

¹²⁶ Jordan Allen et al., *Coronavirus in the U.S.: Latest Map and Case Count*, N.Y. TIMES, <https://www.nytimes.com/interactive/2020/us/coronavirus-us-cases.html> (last visited Feb. 14, 2021).

¹²⁷ Robert C. Reiner Jr. et al., *Modeling COVID-19 Scenarios for the United States*, NATURE MED. (Oct. 23, 2020), <https://www.nature.com/articles/s41591-020-1132-9>.

¹²⁸ Laura Hensley, *Why some people still refuse to wear masks*, GLOB. NEWS (July 21, 2020), <https://globalnews.ca/news/7152424/psychology-behind-anti-masks/#:~:text=When%20people%20get%20mixed%20messaging%20or%20don%E2%80%99t%20understand,were%20a%20priority%20during%20fears%20over%20mask%20shortages>.

¹²⁹ U.S. Surgeon General (@Surgeon_General), TWITTER (Feb. 29, 2020, 7:08 AM), https://twitter.com/Surgeon_General/status/1233725785283932160?ref_src=twsrc%5Etfw%7Ctwcamp%5Etweetembed%7Ctwtterm%5E1233725785283932160&ref_url=https%3A%2F%2Fwww.inquirer.com%2Fhealth%2Fcoronavirus%2Fface-masks-hand-washing-coronavirus-protection-20200304.html.

¹³⁰ Joseph G. Allen, *Opinion: Everyone Should Be Wearing N95 Masks Now*, WASH. POST (Jan. 26, 2021, 11:18 AM), <https://www.washingtonpost.com/opinions/2021/01/26/n95-masks-safest-next-best-options/>.

¹³¹ Watkins, *supra* note 84.

¹³² 3M, *supra* note 19.

¹³³ *Id.*; see also Mike Roman, *3M CEO on COVID-19 response: We have a unique and critical responsibility*, 3M (Mar. 22, 2020) (posted by 3M Chairman and CEO Mike Roman on LinkedIn), <https://news.3m.com/3M-CEO-on-COVID-19-response-We-have-a-unique-and-critical-responsibility>.

manufacturer. This would lessen the burden for healthcare workers having to weather another year with insufficient masks.

3M currently has a government contract for production of N95 masks.¹³⁴ The “Department of Defense, in coordination with the Department of Health and Human Services, has signed a \$126 million contract award with 3M for the increased production of 26 million N95 medical-grade masks per month, starting in October 2020.”¹³⁵ Premier, a purchasing company that many hospitals rely on for supplies, conducted a survey in April 2020 and reported that 23% of respondent health systems are burning through N95s at a rate of more than 100 per day, with many holding an inventory of fewer than a 10 days’ supply of masks.¹³⁶ In the survey, “hospitals ranked the supply of N95 respirators *as their top concern*.”¹³⁷ Hospitals have attempted to conserve their supplies through several avenues, “including extending the wear of N95s (a measure followed by 60 percent of respondents), re-using N95s (40 percent), using expired N95s (33 percent), and using industrial N95s (20 percent).”¹³⁸ If hospitals cannot provide staff with sufficient protective equipment, the lives of frontline healthcare workers, and their families, are at risk. A study was published in *The Lancet* concerning the risk of being infected with COVID-19 among frontline workers.¹³⁹ The report described a significantly increased risk of reporting a positive test for COVID-19 among frontline healthcare workers.¹⁴⁰ The authors’ solution was that “[h]ealth-care systems should ensure adequate availability of PPE and develop additional strategies to protect health-care workers from COVID-19, particularly those from Black, Asian, and minority ethnic backgrounds.”¹⁴¹ The study also found an even-further increased risk of positive COVID-19 test results from those healthcare workers reporting PPE reuse or inadequate PPE.¹⁴²

Healthcare workers are often forced to resort to non-valved, multi-layer cloth masks in place of N95s to prevent transmission of COVID-19 from people coughing, sneezing, talking, or breathing while receiving treatment.¹⁴³ While multi-layer cloth masks can block up to 50-70% of the fine droplets and particles attributable to spreading COVID-19,¹⁴⁴ N95

¹³⁴ U.S. DEP’T OF DEF., *supra* note 116.

¹³⁵ *Id.*

¹³⁶ *Premier Surveys Hospitals’ Supply Levels in March*, PREMIER (Mar. 25, 2020), https://www.premierinc.com/newsroom/blog/premier-surveys-hospitals-supply-levels-in-march_

¹³⁷ *Id.* (emphasis added).

¹³⁸ *Id.*

¹³⁹ Long H. Nguyen et al., *Risk of COVID-19 Among Front-Line Health-Care Workers and the General Community: A Prospective Cohort Study*, THE LANCET (July 31, 2020), [https://www.thelancet.com/journals/lanpub/article/PIIS2468-2667\(20\)30164-X/fulltext](https://www.thelancet.com/journals/lanpub/article/PIIS2468-2667(20)30164-X/fulltext) (the COVID Symptom Study app is registered with ClinicalTrials.gov, NCT04331509).

¹⁴⁰ *Id.*

¹⁴¹ *Id.*

¹⁴² *Id.*

¹⁴³ *Scientific Brief: Community Use of Cloth Masks to Control the Spread of SARS-CoV-2*, CTRS. FOR DISEASE CONTROL & PREVENTION (Nov. 20, 2020), <https://www.cdc.gov/coronavirus/2019-ncov/more/masking-science-sars-cov2.html>.

¹⁴⁴ *Id.*

masks can block significantly more. N95 masks had the highest tested protective efficacy of approximately 80-90% reduction in particulates and droplets reaching the wearer.¹⁴⁵ It is true that healthcare professionals are always at higher risk of exposing themselves and their families to disease.¹⁴⁶ Many individuals are asymptomatic carriers and the COVID-19 virus has a lengthy incubation time of up to fourteen days.¹⁴⁷ This makes the virus highly susceptible to transfer between unknowing individuals who display few or no symptoms, and the odds are even greater for healthcare workers and their families.

VII. DRAWBACKS, DISINCENTIVES TO THIS POLICY

A. Private Patent Holders

The cost of obtaining a patent for an invention generally ranges from \$5,000 to over \$16,000, taking into account the complexity of the invention.¹⁴⁸ A new kind of paperclip, for example, an extremely simple invention, will average between \$5,000 to \$7,000 in attorney and filing fees.¹⁴⁹ Alternatively, highly complex products, such as satellite technologies, MRI scanners, or software patents have a baseline of \$14,000 but can easily cost more.¹⁵⁰ International patents, depending on the number of countries involved,¹⁵¹ can cost over \$100,000.¹⁵² Pharmaceutical patents can cost upwards of millions or billions of dollars when considering Food and Drug Administration (FDA)-required research, development, and clinical trials.¹⁵³ Given the significant costs for patentable technology, it follows that many patent holders may become distressed at the idea of such patents being taken and licensed on a compulsory basis by the federal

¹⁴⁵ Hiroshi Ueki et al., *Effectiveness of Face Masks in Preventing Airborne Transmission of SARS-CoV-2*, 5 AM. SOC'Y MICROBIOLOGY 1, 3 (2020).

¹⁴⁶ Robert H. Shmerling, *What's It Like to be a Healthcare Worker in a Pandemic?* HARVARD HEALTH PUBL'G (Apr. 8, 2020), <https://www.health.harvard.edu/blog/whats-it-like-to-be-a-healthcare-worker-in-a-pandemic-2020040819485>.

¹⁴⁷ HARVARD HEALTH PUBL'G, *If You've Been Exposed to the Coronavirus*, HARVARD MED. SCH. (Aug. 9, 2021) (the time from exposure to symptom onset, known as the incubation period, is thought to be two to fourteen days, though symptoms typically appear within four or five days after exposure.).

¹⁴⁸ *How Much Does a Patent Cost?*, THERVO, <https://thervo.com/costs/how-much-does-a-patent-cost> (last visited Feb. 13, 2021).

¹⁴⁹ *Id.*

¹⁵⁰ *Id.*

¹⁵¹ *Id.* This is because patents only go as far as the domestic borders of the country in which they are procured, unless filed through the Patent Cooperation Treaty.

¹⁵² *Id.*

¹⁵³ See Joseph A. DiMasi et al., *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. HEALTH ECON. 20 (2016) (study of 2013 data estimating that the average total R&D costs for new drug development was \$42.6 billion); see also Aaron E. Carroll, *\$2.6 Billion to Develop a Drug? New Estimate Makes Questionable Assumptions*, N.Y. TIMES (Nov. 18, 2014) (study that came to a different estimate but with 2009 data that said that the average drug development costs ranged from \$161 million to \$1.8 billion for R&D of new drugs), <https://www.nytimes.com/2014/11/19/upshot/calculating-the-real-costs-of-developing-a-new-drug.html>.

government. This is especially prevalent in such a developed nation with strict intellectual patent protections.¹⁵⁴

Developing countries are concerned with protecting intellectual property rights due to the continuing debate on how best to balance encouraging innovation with generic utilization and price competition.¹⁵⁵ The patent system in developed countries “provides incentives to speed up their technological progress, enhance their productivity, and improve their world trade position by strengthening their economy.”¹⁵⁶ For instance, once Italy approved a drug patent law in 1978, their pharmaceutical research and development increased by more than 600% in a decade.¹⁵⁷ Without exclusive rights to develop and sell the property, the property owner will likely struggle to recover the cost of their research and development causing a loss in monetary incentive to develop new technologies. “As the progress of advanced countries is mainly due to extensive inventive research, they are concerned about the protection of [intellectual property rights], and they oppose any interference in the exclusive rights of the patentee of the invention.”¹⁵⁸ It is likely, therefore, that a proposal that would give the executive the power to threaten such rights would meet opposition.

Compulsory licensing threatens the prevalence of patent owners in developed nations, as the owners are primarily intellectual property exporters and are thus drawn to countries that will protect their exclusivity both domestically and abroad.¹⁵⁹ Compulsory licensing does offer compensation but the “amount of royalties set by the state granting a compulsory license cannot be considered as an incentive for further research; it is no way near the potential financial benefit which the patent owner would have enjoyed on an exclusive basis.”¹⁶⁰ When compulsory licensing is issued, the calculation of adequate remuneration for payment to the patent’s owner is complicated. This issue is not solved by TRIPS because TRIPS does not provide guidance to determine the meaning of the words “adequate” or “value” of the authorization.¹⁶¹

¹⁵⁴ Cf. GLOBAL INTELL. PROP. CTR., *The Roots of Innovation*, U.S. CHAMBER OF COMMERCE, 111 (5th ed., 2017) (the United States was ranked first out of forty-five other nations in the United States Chamber’s International IP Index with its key areas of strength including the governments deterrent civil and criminal remedies and being on par with the top five economies’ average core on enforcement.) [hereinafter GLOB. INTELL. PROP. CTR.].

¹⁵⁵ See generally Henry G. Grabowski et al., *The Roles of Patents in Research and Development Incentives in Biopharmaceutical Innovation*, 34 HEALTH AFFS. 302 (2015) (arguing that, while biopharmaceutical R&D is a lengthy, costly, and risky process, government research and development contracting could fulfill a useful role in addressing unmet needs.), <https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.2014.1047>.

¹⁵⁶ Muhammad Z. Abbas, *Pros and Cons of Compulsory Licensing: An Analysis of Arguments*, 3 INT’L J. SOC. SCI. & HUMAN. 254, 254 (2013) (internal quotation omitted).

¹⁵⁷ Richard J. Hunter et al., *Compulsory licensing: a major IP issue in international business today?* 11 EUROPEAN J. SOC. SCI. 370, 376 (1993).

¹⁵⁸ Abbas, *supra* note 156.

¹⁵⁹ Dina Halajian, *Inadequacy of TRIPS & the Compulsory License: Why Broad Compulsory Licensing is Not a Viable Solution to the Access Medicine Problem*, 38 BROOK. J. INT’L L. 1191, 1193 (2013).

¹⁶⁰ Abbas, *supra* note 156, at 254–55.

¹⁶¹ Halajian, *supra* note 159, at 1210.

B. The Government(s), both Domestic and Foreign

The Federal Government has gain and loss calculations to assess each transaction under the DPA.¹⁶² This would be a safeguard to patent holders, before the government would decide if compulsory licensing would solve a given intellectual property hurdle, national emergency, or global pandemic.¹⁶³ The United States has the most stringent and rigid patent protection laws in the world;¹⁶⁴ however, the argument can be made that,

[Since a] patent is a privilege granted to the patent holder by the state, government of the state can therefore limit that privilege ... [this] concept came to the limelight after outbreak of pandemics like HIV/AIDS as the issue of access to necessary drugs emerged as an important global issue.¹⁶⁵

The exercise of government authority over rights granted to citizens is sometimes necessary—similarly to the control exercised during the HIV/AIDS pandemic—to prevent further hardship upon the entire population. The government bestows upon its citizens certain rights; however, the rights are mere privileges that can be limited or removed particularly in times of great calamity or necessity.

Compulsory licensing is not an easy process. TRIPS requires that several procedural hurdles be overcome before this step can be taken.¹⁶⁶ For a developing country, obtaining a compulsory licensing right entails initial delays from judicial review.¹⁶⁷ The delays caused by judicial review discourage licensees from generic production in various ways, including decreasing time to recover startup costs and increasing the potential for failure.¹⁶⁸ Some of the procedural requirements a country must satisfy before obtaining compulsory licensing include: 1) the license use must be considered on its individual merit; 2) the limited scope and duration of the use must be reported; 3) review of the use authorization by either judicial or independent bodies; and 4) adequate remuneration to the owner must be settled (taking into account the economic value of the license), subject to further judicial or independent review.¹⁶⁹

¹⁶² Authority to Review Certain Mergers, Acquisitions, and Takeovers 50 U.S.C. §4565(l).

¹⁶³ *Id.*

¹⁶⁴ GLOB. INTELL. PROP. CTR., *supra* note 154.

¹⁶⁵ Abbas, *supra* note 156, at 255.

¹⁶⁶ Agreement on Trade-Related Aspects of Intellectual Property Rights art. 31, Apr. 15, 1994, 33 ILM 1197 [hereinafter TRIPS].

¹⁶⁷ See generally Donald Harris, *TRIPS After Fifteen Years: Success or Failure, as Measured by Compulsory Licensing*, 18 J. INTELL. PROP. L. 367, 390–92 (2011).

¹⁶⁸ See generally *id.*

¹⁶⁹ *Id.* at 384; see also Cynthia M. Ho, *A New World Order for Addressing Patent Rights and Public Health*, 82 CHI.-KENT L. REV. 1469, 1488 (2007).

Compulsory licenses had an uptick in usage in 2005,¹⁷⁰ and have been discussed in the current COVID-19 global pandemic.¹⁷¹ They were primarily utilized during the HIV/AIDS global pandemic to distribute a necessary drug.¹⁷² Canada used a compulsory license to export a generic AIDS drug to Rwanda in 2008.¹⁷³ “[D]ue to the complicated process . . . lack of incentives, huge costs, time commitment, and challenges in recovery costs . . .”¹⁷⁴ the ability to obtain a compulsory license through TRIPS is more difficult than intended by its writers, who sought to assist with patent limitations when health and human need outweighs intellectual property rights.¹⁷⁵ By the end of 2009, only 36% of the people who needed the antiretroviral had received it.¹⁷⁶ Working to clarify the “scope” of a legitimate compulsory licensing would help businesses become more accepting. For a government, this is difficult. There is a balance between better defining the scope and defining it too openly.¹⁷⁷ Better defining the scope would allow involved persons to have proper notice of the disruption of their patent holding.¹⁷⁸ Contrarily, defining it too broadly could open a floodgate and destroy a wide array of patents.¹⁷⁹

The United States has improved distributions regarding national stockpile supplies as exemplified during the H1N1 epidemic distribution during the Obama administration; however, in developing nations, distribution is much more difficult due to a lack of infrastructure necessary for transporting supplies.¹⁸⁰ This is particularly true during a global pandemic or national emergency.¹⁸¹ The human right to health has been recognized in the national constitutions of at least 135 states as of 2005.¹⁸² Despite this fact, access to essential medicines—a prerequisite to the right of health—is only recognized as a right in five states.¹⁸³ This lack of recognition makes it harder for countries to justify compulsory licensing for

¹⁷⁰ See generally James Packard Love, *Recent Examples of The Use of Compulsory Licenses on Patents*, 2007 KNOWLEDGE ECOLOGY INT’L 1 (May 6, 2007), http://www.keionline.org/misc-docs/recent_cls.pdf.

¹⁷¹ Wong, *supra* note 107.

¹⁷² Halajian, *supra* note 159, at 1206.

¹⁷³ *Id.* at 1203.

¹⁷⁴ *Id.*

¹⁷⁵ Cf. TRIPS, *supra* note 166 (arguing that the TRIPS Agreement was to promote effective and adequate protection of intellectual property rights but to also ensure that these measures of protection did not themselves bar legitimate trade of goods or development of intellectual property among the least-developed nations who needed to create a sound and viable technological base.).

¹⁷⁶ *Id.*

¹⁷⁷ *Id.* at 1222.

¹⁷⁸ *Id.*

¹⁷⁹ *Id.*

¹⁸⁰ UNION OF INT’L ASS’NS, *Inadequate transport infrastructure*, THE ENCYCLOPEDIA OF WORLD PROBS. & HUM. POTENTIAL (July 22, 2021, 8:27 PM), <http://encyclopedia.uia.org/en/problem/135799>.

¹⁸¹ *Id.* (arguing that the aggravates of inadequate infrastructure and distribution would include inadequate disaster rescue and relief and ineffective means for goods supply and distribution which would only be exacerbated during a pandemic or national emergency.).

¹⁸² Dilip K. Das, *Intellectual Property Rights and the Doha Round*, 8 J. WORLD INTELL. PROP. 33 (2005).

¹⁸³ See generally Rudolf V. Van Puymbroeck, *Basic Survival Needs and Access to Medicines-Coming to Grips with TRIPS: Conversion and Calculation*, 38 J. L. MED. & ETHICS 520, 523 (2010).

drugs to handle health-related needs. The government that relies solely on its ability to purchase goods and store them for use, as the SNS exemplifies, is left in a position of the proverbial between a rock and a hard place, when either that stockpile is not maintained properly or it simply lacks the required materials and goods because they were not anticipated as a need.

C. Private Citizens

The purpose of compulsory licenses is to solve procurement issues related to costly drugs and technologies that people need access to for their daily lives, national emergencies, or global pandemics. Failing to protect intellectual property rights would adversely affect access to essential medicines due to the increased reluctance of pharmaceutical and technological firms to develop products in countries lacking patent protection,¹⁸⁴ especially if they were likely to be subject to a compulsory license. Additionally, private citizens face certain risks if the patent owner is no longer the sole producer of a developed good. Companies that are granted licenses may only have a brief time to prepare to produce. These companies may lack access to the same material supply chains, to adequate time to train their personnel, or to the financial gain of exclusively producing the good. These are all motives for a company to sacrifice quality of the product.

Compulsory licenses can raise safety concerns due to the possibility that situations may arise where unapproved generics become widely available.¹⁸⁵ In Thailand, unbranded clopidogrel, efavirenz, and lopinavir/ritonavir will continue to be imported from India until the Government Pharmaceutical Organization (GPO) develops the capacity to make a sufficient amount of the drugs;¹⁸⁶ however, the FDA has only tentatively approved the generic efavirenz made by Aurobindo Pharma Ltd and Cipla Ltd.¹⁸⁷ In contrast, the FDA has not recognized the remaining generic products as equivalent.¹⁸⁸ With unregulated drugs on the market, citizens' must put their health on the line and do a risk analysis between taking unverified compounds or fighting illness without drug intervention. The human right to health is paramount, and it deserves not just recognition, but active protection. This entails ensuring that compulsory licenses are only granted to manufacturers who can sufficiently produce the licensed products, which should also be validated by appropriate agencies to ensure they are generic equivalents to the original patent.

Private citizens also have a specific concern when it comes to the 3M patent since they are not required to wear this specific type of face covering.

¹⁸⁴ Abbas, *supra* note 156, at 257.

¹⁸⁵ Ed Lamb, *Compulsory Licensing: A Necessary Evil?*, PHARMACY TIMES (June 1, 2007), <https://www.pharmacytimes.com/view/2007-06-6564>.

¹⁸⁶ *Id.*

¹⁸⁷ *Id.*

¹⁸⁸ Lamb, *supra* note 185.

If producers are contracted to mass-produce the N95 mask, cloth and other facial coverings may become less available or more expensive. “Two-thirds of Americans reported being in close contact (within less than [six] feet) with people outside their household in early December, but only about half of them said they mostly or always wore a mask while doing so.”¹⁸⁹ The private citizens of countries will have to worry about generic masks that are potentially lower quality and less protective, and/or suffering from the market being flooded with a product not useful for everyday life. That is not to say that N95s should not be worn by as many individuals as possible. More private citizens would be protected if healthcare and frontline workers had sufficient N95s to limit exposure.

Debating and speculation on what the market may or may not do if compulsory licensing were granted for the right to produce N95 masks by non-3M manufacturers is purely that, speculation. Private intellectual property holders are unlikely to appreciate competitors (existing or new) benefiting from government contracts to produce their products under a compulsory license. The aforementioned market change on cloth masks being replaced by N95’s as a readily available resource is only hypothetical and provides little in form for actual arguments for or against the proposed language of this note. The point that it does serve is that there is an incentive for other manufacturers to seek out an N95 contract with the government if it should take place. The government contract between the DOD and 3M for N95’s offered a purchase price of approximately \$4.80 per mask, while pre-COVID-19 N95s were sold on the private market for roughly between \$0.50 and \$1.00 per mask.¹⁹⁰ The increase in profit will likely draw many interested parties, including some that might normally be producing other goods for market, towards producing N95s.

CONCLUSION

Among the many public health challenges faced in the first year of the COVID-19 pandemic, mask availability was a huge obstacle to protecting citizens.¹⁹¹ The situation could have been improved if the executive branch had seized the N95 patent in February or March of 2020; however, due to a privately held patent for a single piece of personal protective equipment, the United States lost the ability to control N95 production as a nation. Notably, the United States lost this ability before the government or healthcare

¹⁸⁹ Jim Key, *Half of U.S. Adults Don’t Wear Masks When in Close Contact with Non-household Members*, UNIV. S. CALIF. DORNSIFE (Jan. 21, 2021), <https://dornsife.usc.edu/news/stories/3388/understanding-coronavirus-in-america-mask-use-among-us-adults/>.

¹⁹⁰ Cf. Jay Root & Shannon Najmabadi, *Someone Says They Have N95 Masks for Sale. The Asking Price is Six Times the Usual Cost*, THE TEX. TRIB. (Mar. 31, 2020), <https://www.texastribune.org/2020/03/31/texas-company-offered-n95-masks-amid-coronavirus-6-times-usual-price/> (as healthcare professionals beg for supplies to protect themselves from COVID-19 infection, a Texas company found a seller with at least 2 million masks and quietly offered them for sale at \$6 each. Before the pandemic, they cost around \$1).

¹⁹¹ Coy, *supra* note 22.

industry truly understood COVID-19 transmission and the preventative efficacy of cloth masks. Continuing to rely on 3M to increase production on their own for the next year is still a risk, especially as the fate of the pandemic is ever-changing in the battle between vaccine and variant.¹⁹² The study conducted by the University of Washington’s Institute for Health Metrics and Evaluation estimates that as of September 21, 2020, only 49% of Americans reported consistent mask use in public settings.¹⁹³ By February 14, 2021, the daily number of cases had risen to 7,689, with daily deaths up an average of 5% every week.¹⁹⁴ Given the infection rate and death toll, if estimated death projections are even somewhat accurate, we could save more than 100,000 lives just by having an estimated 95% or higher mask-wearing percentage.¹⁹⁵ It is impossible, with the current production level, to provide that kind of supply of N95 masks without the patent held by 3M being distributed to more companies than just its holder. Increased production of N95s could have at least limited the estimated “3,000 United States healthcare workers” that have died due to COVID-19 as of January 8, 2021.¹⁹⁶ This scenario has demonstrated that often a single piece of equipment or technology can turn the tide on deadly pandemic statistics, and in this crisis and those in the future, compulsory licensing could be key.

When great need arises, we must ask, incentivize, or—in extreme situations—take from the few (with every effort to rectify damages) for the good of the nation. In this case, and likely others in the future, the best option is to incentivize through compulsory licensing.

¹⁹² Cf. MCANDREW ET AL., *supra* note 125.

¹⁹³ Jason Slotkin, *Universal Mask Wearing Could Save Some 130,000 Lives in The U.S.*, *Study Suggests*, NAT’L PUB. RADIO (Oct. 24, 2020), <https://www.npr.org/sections/coronavirus-live-updates/2020/10/24/927472457/universal-mask-wearing-could-save-some-130-000-u-s-lives-study-suggests>.

¹⁹⁴ CTRS. FOR DISEASE CONTROL & PREVENTION, *supra* note 13.

¹⁹⁵ Slotkin, *supra* note 193.

¹⁹⁶ Niall McCarthy, *Where U.S. Healthcare Workers Have Died from Covid-19*, STATISTA (Jan. 8, 2021), <https://www.statista.com/chart/23882/healthcare-worker-deaths-by-state/>.