









ABORTION ACCESS: A POST-*ROE* PUBLIC HEALTH EMERGENCY SEPTEMBER 9, 2022

On June 24, 2022, the U.S. Supreme Court in <u>Dobbs v. Jackson Women's Health Organization</u> (Dobbs) fully overturned *Roe v. Wade* (Roe) and *Planned Parenthood v. Casey* (Casey), cases which upheld constitutional rights to abortion. In the aftermath, legal authorities to regulate and even ban abortion have shifted to state (or local) governments. Profound national reactions and public health repercussions may necessitate extraordinary responses, including the potential use of federal emergency response powers. This Memo briefly outlays federal emergency declarations and powers focused on this outcome.

I. Potential Public Health Risks of Lack of Abortion Access

Emergency authorities available to the President and other federal officials may be implicated in the aftermath of the Supreme Court's overturning of *Roe* and *Casey*. Prior to *Dobbs*' issuance, the Guttmacher Institute postulated that <u>as many as 26 states</u> would act to ban abortion in some form post-*Roe*. States are now attempting to seek enforcement of pre-*Roe* state-based legislative bans, "trigger" laws designed to snap into place upon *Roe*'s overturning, near-total, six-, and eight-week bans, and state constitutional provisions expressly disavowing abortion rights.

As states begin curbing abortion access and procedures post-*Dobbs*, potential impacts on neighboring jurisdictions seeking to preserve abortion care could be profound. Illinois, Minnesota, New Mexico, and other states could face surges of patients from nearby states banning abortion. Women experiencing lower incomes, women of color, and young women may lack the means to pay for or travel long distances to obtain abortion care. They are especially at risk of increased poor health outcomes or death in the nation with the highest maternal mortality rates in the industrialized world.

A study published in Demography in December 2021 indicated that if all wanted abortions in the U.S. were denied, mortality would ultimately increase by 21% for all pregnant individuals and 33% in non-Hispanic black populations in subsequent years after the first year of such a ban, simply by virtue of continuing the pregnancy (i.e., not including potential deaths caused by resorting to unsafe abortions). While not *all* persons seeking abortions will be denied should *Roe* fall, these data demonstrate potential severe public health impacts that selectively denying abortions can have on populations, potentially contributing to a national (or regional) public health emergency (PHE).

II. Federal Emergency Declarations and Powers

A series of federal statutes provide distinct emergency powers implicated in PHEs including the **Robert T. Stafford Disaster Relief and Emergency Assistance Act** ((Stafford Act), 42 U.S.C.A. § 5121 et seq.); **National Emergencies Act** ((NEA), 50 U.S.C.A. §§ 1601, 1621-1622, 1631, 1641, 1641); **Public Health Service Act** ((PHSA), 42 U.S.C.A. § 201 et seq.); **Public Readiness and Emergency Preparedness Act** ((PREP Act), 42

U.S.C. § 247d-6d); Pandemic and All-Hazards Preparedness Act ((PAHPA), Pub. L. No. 109-417, 120 Stat. 2831 (2013)); Project BioShield Act of 2004 (Pub. L. No. 102-276, 118 Stat. 835 (2004)); and Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Pub. L. No. 107-188, 116 Stat. 594 (2002)). Relevant observations and potential applications of these statutes are discussed below.

A. National Emergencies

The Stafford Act empowers the President to assist multiple actors during emergencies, primarily state and local governments. It defines "emergency" as including "any occasion or instance for which, in the determination of the President, Federal assistance is needed to supplement State and local efforts and capabilities to save lives and to protect property and public health and safety" Typically upon request by a state governor the President can declare an emergency that enables further provision of federal assistance, including directing federal agencies to use their authorities and resources, assisting in distributing medicine and emergency resources, coordinating relief assistance, and providing accelerated support or assistance without a specific state or local government request where necessary.

NEA lays out a procedural framework for a presidential emergency declaration. Although "emergency" is not expressly defined, the Act <u>enables the President to declare one</u> with immediate transmission of the same to Congress. NEA further <u>requires</u> that the powers be supported by separate provisions of law enabling their use. <u>Certain provisions of law are excepted from NEA application</u>, including Chapters 1-11 of Title 40 (regarding federal property) and several other provisions relating to government contracts.

The Stafford Act and NEA are broad and permissive. Stafford Act emergencies encompass actions necessary to assist state and local responders to "save lives" and "protect . . . public health and safety," which may be sufficiently broad to apply to severe health consequences of simultaneous and broad abortion health care bans in numerous states. The Stafford Act typically requires a governor to request a presidential declaration, which states banning abortion will not likely seek. Rather, states attempting to protect and support abortion health care may request assistance if substantial numbers of patients overwhelm available abortion care facilities. Conversely, NEA does not require a gubernatorial request and does not expressly define the terms by which a declaration may be made, potentially allowing broader applications. NEA has been invoked previously in distinct circumstances to address export and trade controls, weapons proliferation, the 9/11 terrorist attacks, H1N1 influenza, and COVID-19.

B. Public Health Emergencies

PHSA empowers the federal Secretary of the Department of Health and Human Services (HHS) to declare a PHE. "Public health emergency" is not expressly defined within the Act. Rather, a PHE declaration may be made on the basis of either (1) a "disease or disorder" which "presents a [PHE]" or (2) a "[PHE], including significant outbreaks of infectious diseases or bioterrorist attacks, otherwise exists." PHSA does not require that a governor request a declaration. HHS' Secretary may issue a declaration independently of states, but most often with White House approval. HHS' declaration of a PHE enables specific response measures, including entering into expedited contracts or issuing grants; utilizing the PHE Fund for rapid response; and adjusting Medicare reimbursements for Part B drugs.

PHSA's permissive language may enable its use in responding to abortion health care needs as a PHE. PHSA has been used broadly in the past to respond to floods, tornados, infectious disease outbreaks, as well as diverse risks such as the opioid crisis and Presidential Inaugurations. Non-binding guidance suggests that the Secretary may not declare a "potential" PHE. However, the Secretary has discretion to determine that a set of circumstances "presents' a PHE or a PHE otherwise exists, based on conditions that exist prior to the actual outbreak of disease or natural catastrophe." PHEs may also be declared on a specific date with retroactive

applications. Thus, for example, HHS' PHE regarding COVID-19 was issued by Secretary Alex Azar on January 31, 2020 but was applied retroactively to January 27.

C. Emergency Waivers

PHSA, Stafford Act, and NEA intersect to enable waiving certain provisions of the Social Security Act (SSA) respecting Medicare, Medicaid/CHIP and HIPAA. Known as <u>Section 1135 waivers</u> these require (1) a Presidential emergency declaration pursuant to either NEA or Stafford Act, *and* (2) a PHE declaration by HHS' Secretary pursuant to PHSA. When implicated, <u>Section 1135</u> allows extensive waivers, including:

- Specific "conditions of participation or other certification requirements" for health care providers or specific types of providers, including "pre-approval requirements;"
- Medical licensure requirements limiting health care workers (in good standing) to practice only in states in which they are actively licensed; and
- Penalties for transfers of patients with emergency medical conditions or in active labor who were not stabilized as typically required via the Emergency Medical Treatment and Active Labor Act (EMTALA).

D. PREP Act Provisions

The <u>PREP Act</u> authorizes HHS' Secretary to issue a PREP Act Declaration to recommend, "under conditions as the Secretary may specify, the manufacture, testing, development, distribution, administration, or use of one or more covered countermeasures." These measures may include qualified pandemic or epidemic products, security countermeasures, products subject to an Emergency Use Authorization (EUA), and NIH-approved respiratory devices.

Qualified pandemic or epidemic products include products which are intended to "diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic; or to limit the harm such pandemic or epidemic might otherwise cause," as well as products enhancing the effects of, or addressing conditions caused by, the aforementioned products. This can include approved products or products subject to EUAs. Security countermeasures include drugs, biologics, and devices to "diagnose, mitigate, prevent, or treat harm from any biological, chemical, radiological, or nuclear agent identified as a material threat." "Material threats" are determined in partnership with the Homeland Security Secretary and are "sufficient to affect national security."

<u>A PREP Act declaration</u> may include strong liability protections with respect to losses incurred via covered countermeasures. The PREP Act <u>broadly preempts</u> different and conflicting state laws, as well as laws relating to use, "prescribing, dispensing, or administration by qualified persons of the covered countermeasure," or otherwise relating to any requirement applicable to covered countermeasures under (i) the Food and Drug Cosmetic Act (FDCA) or (ii) 42 U.S.C. Title 42, Chapter 6A (addressing the Public Health Service).

During the COVID-19 pandemic, for example, <u>PREP Act declarations provided liability protections</u> for multiple persons and entities ordering or administering COVID-19 vaccines, including providers (i) practicing in states other than where they were actively licensed, (ii) who were retired or on inactive license status; or (iii) whose licenses would not ordinarily permit them to engage in such efforts, including pharmacists or their interns, EMTs, midwives, dentists, and optometrists.

Contrary state or local laws or policies may be extensively preempted via the PREP Act. For example, in October 2020 during the pandemic, HHS' Assistant Secretary for Preparedness and Response (ASPR) <u>asserted PREP Act preemption</u> when Nevada state officials attempted to block usage of certain COVID-19 tests subject to an EUA in their state. Nevada officials claimed the tests were unreliable, but <u>subsequently were required to allow use of the tests in their state</u>.

Theoretically, the PREP Act could be leveraged to convert abortion-inducing drugs, including mifepristone and misoprostol, into covered countermeasures for purposes of utilizing the PREP Act's preemption and liability protections. Yet the definition of "covered countermeasures" in the PREP Act is limited. In addition to EUA products and NIH-approved respiratory devices, the definition includes qualified epidemic and pandemic products and security countermeasures. Because "epidemic" and "pandemic" are not defined in the Act, a large-scale need for abortion care may arguably not invoke the PREP Act under standard definitions of "pandemic" or "epidemic." While <u>current PREP Act declarations</u> cover Zika, Ebola, Smallpox, COVID-19, Marburg disease, botulinum toxin, Acute Radiation Syndrome, insecticides, and Anthrax, abortion medications seem distinct. It is also unclear whether a large-scale need for abortion care would count as a biological "agent" substantial to the point of affecting national security.

<u>EUAs</u> may be issued for unapproved drugs, but also to allow for *unapproved uses* of approved drugs. This latter authority could apply to <u>misoprostol</u>, <u>which is approved for prevention of NSAID-induced gastric ulcers</u> and <u>not specifically approved</u> for inducing abortions. <u>Mifepristone</u>, however, is FDA-approved specifically for this use, so EUA authority would likely not apply.

E. Additional Federal Laws

<u>PAHPA</u> provides a series of authorities, including requiring HHS' Secretary to <u>"oversee the implementation of the National Preparedness goal of taking into account the public health and medical needs of at-risk individuals in the event of a [PHE]." "At risk" individuals include <u>"pregnant women" and "other individuals who have special needs in the event of a [PHE]." Additional measures allow for the deployment of commissioned corps officers and collaborations to address medical surge capacity.</u></u>

The <u>Project Bioshield Act of 2004</u> established the <u>Strategic National Stockpile</u>, a stockpile of drugs, biologics, medical devices and other products to provide "for the emergency health security of the United States." The <u>Public Health Security and Bioterrorism Preparedness & Response Act of 2002</u> amended PHSA in part to authorize HHS' Secretary to activate ASPR's National Disaster Medical System (NDMS).

NDMS is a collaboration between HHS, the Department of Homeland Security (DHS), the Department of Defense, and the Department of Veterans Affairs. It can be (1) used to provide health and health-related services for victims of a PHE—regardless of whether a PHE has been declared—or (2) stationed at locations that HHS' Secretary believes to be at substantial risk for a PHE (such as states with abortion ban trigger laws).

A <u>2015 CRS Report</u> clarifies HHS' Secretary's "broad . . . authority to deploy NDMS components. No specific statutory trigger or threshold is required," and NDMS deployed personnel are considered federal employees protected from select liability claims. In the context of abortion access, <u>Disaster Medical Assistance Teams</u> (<u>DMATs</u>) comprised of various healthcare providers capable of administering general medical services may be instrumental. Additional information on NDMS is available via <u>HHS' 2021 report</u> and <u>Kaiser Family Foundation's 2022 Issue brief</u>.

III. Limitations of Federal Emergency Powers

Statutory language of the above authorities presents a limitation warranting consideration, particularly in terms of the potential for litigation and resulting stringent judicial interpretations. Definitions including "public health emergency," "covered countermeasure," and restrictions on specific uses of Section 1135 waivers could provoke challenges, with the potential for deferential or limiting interpretations from courts.

With respect to the PREP Act, <u>circuit court</u> decisions in 2021 and 2022 have remanded challenges to state court on jurisdictional grounds, concluding that the PREP Act <u>"does not entirely supplant state law claims, including claims of general negligence and recklessness."</u> The United States Court of Appeals for the Eleventh Circuit is

considering whether to affirm a lower court decision concluding that the PREP Act does not completely preempt state law. These cases may shape future preemptive effects of the PREP Act, leaving in place certain claims to be addressed in state courts and establishing a federal cause of action only for cases involving willful misconduct. Additional questions subject to further litigation include whether certain activities constitute "use" of a covered countermeasure subject to PREP Act immunity.

IV. Intersection of Federal Emergency Powers with State Laws and Prohibitions

The federal government has preemptive powers in areas under its jurisdiction, including issues of national security. Federal law generally preempts conflicting state law, but certain statutory provisions such as the PREP Act include broad <u>express preemption provisions</u>. State governments may thus be prevented from blocking or contesting certain federal actions on preemption grounds.

However, as seen throughout the COVID-19 pandemic, courts considering state-based legal challenges to federal interventions have overruled federal agency actions despite strong evidence that such measures are in the public's interest. In *Florida v. Becerra* (6/18/2021), for example, a federal district court judge held that the Centers for Disease Control and Prevention (CDC) lacked authority to restrict cruise ship travel during the pandemic, which was <u>upheld on appeal in the 11th Circuit</u>. In *Alabama Association of Realtors v. HHS* (8/26/2021), the Supreme Court held that CDC lacked the power to issue a nationwide eviction moratorium irrespective of strong public health justification for CDC's intervention during the pandemic. In mid-April 2022, in *Health Freedom Defense Fund v. Biden* (4/18/2022), a federal district court judge based in the Middle District of Florida rejected CDC's travel mask requirement. Against the backdrop of these types of decisions, <u>public health experts are concerned</u> about the federal government's ability to address future PHEs.

An additional pending case has the potential to cabin *state* action vis-à-vis federal preemption. In October 2020, GenBioPro, Inc. <u>filed a complaint</u> against Dr. Thomas Dobbs, the State Health Officer of the Mississippi Department of Health, regarding Mississippi's laws that substantially restrict mifepristone's use beyond what the Food and Drug Administration (FDA) has deemed is safe. GenBioPro wants to stop enforcement of Mississippi's mifepristone laws on 2 grounds: (1) FDA's regulation of mifepristone preempts any conflicting state regulation, and (2) Mississippi's regulations disrupt the uniform application of FDA's nationwide regulations. GenBioPro voluntarily dismissed the case after Dobbs, but subsequent cases addressing similar legal arguments may substantially affect accessibility of medication abortion moving forward.

Additional Resources

The Network for Public Health Law has developed (and is regularly updating) <u>a series of reproductive health resources</u> in the aftermath of the *Dobbs* decision, including: (1) <u>Abortion Access: Post-Dobbs Litigation Themes</u>; (2) <u>Ballot Measures on Abortion Access</u>; (3) <u>State-Based Abortion Protections</u>; (4) <u>Abortion Access: A Post-Roe</u> Public Health Emergency.

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