The Razor's Edge

The case of *Estate of Maglioli v. Alliance HC Holdings, LLC*, 2021 U.S. App. LEXIS 31526 (3rd Cir. October 20, 2021) (Porter, C.J.) walks the razor's edge. The razor's edge divides the reach of the United States Constitution between the national government and the province of the States. As we know, powers not delegated to the national government remain with the people in the States. See *Bond v. United States*, 564 U.S. 211, 221 (2011); The Federalist No. 45 (James Madison). The United States Court of Appeals for the Third Circuit observed that the "pandemic has tested our federal system, but this case confirms its resilience." The Court worked hard to respect constitutional powers in the face of pandemic panic.

The Court observed that defendants invited the judiciary to assert the "judicial Power of the United States" over a matter that belonged to the States. U.S. Const. art. III. The Court declined that invitation. The Circuit determined that it would not exercise power that the Constitution and Congress had not given to the federal judiciary. "There is no COVID-19 exception to federalism." At slip opinion p. ___.

Joseph Maglioli, Dale Petry, Wanda Kaegi, and Stephen Blaine were residents of two different New Jersey nursing homes. Tragically, they died from COVID-19. Their estates claim that the nursing homes acted negligently in handling the COVID-19 pandemic, causing the residents' deaths. The estates commenced negligence and wrongful-death lawsuits against the nursing homes in state court on behalf of themselves, the family members of the deceased, and residents similarly situated. The nursing homes removed to federal court, but the District Court dismissed the cases for lack of subject-matter jurisdiction and remanded them to state court. The nursing homes appealed, arguing that the District Court has three independent grounds for federal jurisdiction: federal officer removal, complete preemption of state law, and the presence of a substantial federal issue. We disagree. The estates have not invoked the power of the federal courts, and Congress has not given us power to take this case from the state court. The Third Circuit affirmed the District Court's order dismissing the cases for lack of jurisdiction.

In 2005, Congress passed the Public Readiness and Emergency Preparedness Act ("PREP Act"), 42 U.S.C. §§ 247d-6d, 247d6e. The PREP Act protects certain covered individuals—such as pharmacies and drug manufacturers—from lawsuits during a public-health emergency. The Act lies dormant until invoked by the Secretary of the Department of Health and Human Services ("HHS"). If the Secretary deems a health threat a public-health emergency, he may publish a declaration in the Federal Register recommending certain "covered countermeasures." Id. § 247d-6d(b)(1). When the Secretary makes such a declaration, the covered individuals become immune from suit and liability from claims related to the administration of a covered countermeasure. Id. § 247d6d(a)(1).

In March 2020, the Secretary issued a declaration under the PREP Act, declaring that COVID-19 is a public-health emergency. See Declaration Under the PREP Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15,198, 15,201 (Mar. 17, 2020). The Secretary recommended a series of covered countermeasures that includes drugs, devices, and products "used to treat, diagnose, cure, prevent, or mitigate

COVID-19," subject to the PREP Act's definitions. Id. at 15,202. The Secretary has since amended the declaration seven times. See Seventh Amendment to Declaration Under the PREP Act for Medical Countermeasures Against COVID-19, 86 Fed. Reg. 14,462 (Mar. 16, 2021). HHS has also issued advisory opinions and guidance letters on various issues related to the declaration.

The Secretary controls the scope of immunity through the declaration and amendments, within the confines of the PREP Act. A covered person enjoys immunity from all claims arising under federal or state law that relate to the use of a covered countermeasure. 42 U.S.C. § 247d-6d(a)(1). Covered persons include manufacturers, distributors, program planners, and qualified persons, as well as their officials, agents, and employees. 85 Fed. Reg. at 15,201.

The scope of immunity is broad. Covered persons are immune from "any claim for loss that has a causal relationship with the administration to or use by an individual of a covered countermeasure." 42 U.S.C. § 247d-6d(a)(2)(B). That includes claims relating to "the design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, or use of such countermeasure." Id.

What happens to the claims blocked by PREP Act immunity? Congress did not leave those injured by covered countermeasures without recourse. The Act establishes a fund to compensate "eligible individuals for covered injuries directly caused by the administration or use of a covered countermeasure." Id. § 247d-6e(a). The Secretary has broad authority to issue regulations determining who and what types of injuries qualify for compensation under the fund. Id. § 247d6e(b)(4)–(5).

There is one exception to this statutory immunity. The PREP Act provides "an exclusive Federal cause of action against a covered person for death or serious physical injury proximately caused by willful misconduct." Id. § 247d6d(d)(1). "Willful misconduct" is in turn defined as "an act or omission that is taken—(i) intentionally to achieve a wrongful purpose; (ii) knowingly without legal or factual justification; and (iii) in disregard of a known or obvious risk that is so great as to make it highly probable that the harm will outweigh the benefit." Id. § 247d-6d(c)(1)(A). The Act clarifies that willful misconduct "shall be construed as establishing a standard for liability that is more stringent than a standard of negligence in any form or recklessness." Id. § 247d-6d(c)(1)(B). Notwithstanding the statutory definition, the Secretary may issue regulations that further restrict what acts or omissions qualify as willful misconduct. Id. § 247d-6d(c)(2)(A).

The estates alleged that the residents' deaths "were a direct result of [the nursing homes'] failures to take measures to protect them at the facilities from the deadly Covid-19 virus, and/or medical malpractice." For example, the estates claim the nursing homes acted negligently by failing to monitor food preparation, failing to provide personal protective equipment, failing to timely diagnose and properly treat the disease, and permitting visitors and employees to enter the facilities without taking their temperatures or requiring them to wear masks.

Nursing homes across the country face similar lawsuits. The story in all of these cases is essentially the same. Estates of deceased nursing-home residents sue the nursing homes in state court, alleging that the nursing homes negligently handled COVID-19.

The nursing homes remove to federal court on the basis of a combination of federal-officer removal, complete preemption, and a substantial federal issue. Nearly every federal district court to confront these cases has dismissed for lack of jurisdiction and remanded to the state court. It appears that the Third Circuit is the first court to decide these troublesome issues.

The Circuit Court did not hold that all state-law causes of action are invulnerable to complete preemption under the PREP Act. Some state law claims could fall within Congress's narrow cause of action for willful misconduct. The Circuit also did not address whether the PREP Act preempts the state's claims under ordinary preemption rules. That is for the state court to determine on remand. The Court only held that (1) the estates' negligence claims based on New Jersey law do not fall under the PREP Act's narrow cause of action for willful misconduct, and (2) the PREP Act's compensation fund is not an exclusive federal cause of action triggering removal jurisdiction.

Finally, the nursing homes argue that the estates' claims raise a substantial federal issue that permits removal under 28 U.S.C. § 1441(a). Like complete preemption, this argument relies on the jurisdiction of federal courts to decide federal questions. To remove a case under federal-question jurisdiction, a defendant must show that the case "aris[es] under" federal law. 28 U.S.C. § 1331; see also id. § 1441(a). Typically, "a case arises under federal law when federal law creates the cause of action asserted." *Gunn v. Minton*, 568 U.S. 251, 257 (2013). As we have discussed, the estates do not assert a federal cause of action. Nevertheless, a small number of state claims may arise under federal law if they raise "significant federal issues." *Grable & Sons Metal Prod., Inc. v. Darue Eng'g & Mfg*., 545 U.S. 308, 312 (2005).

Take-away points:

- Nursing home residents die from COVID-19.
- Claim of negligence by the nursing home.
- In 2005 Congress passed the Public Readiness and Emergency Preparedness Act, which protects pharmacies and drug manufacturers from lawsuits during a public health emergency.
- In March 2020, the Secretary issues a declaration under the PREP Act declaring COVID-19 was a public health emergency.
- The Secretary controls the scope of immunity through declarations and amendments.
- The covered person enjoys immunity from claims under state or federal law.
- Covered persons include manufacturers, distributors, program planners and qualified persons, as well as their officials, agents and employees.
- The scope of immunity is broad.
- For those blocked by the immunity, there is a fund to compensate individuals.
- There is no immunity for intentional wrongdoing; actions knowingly done without legal or factual justification; and disregard of a known or obvious risk.
- The court found that, therefore, the actions against the nursing homes were preempted.

The Court did not address whether the drastic immunity granted under dubious circumstances can be a Fifth Amendment "taking", whether there are substantive due process issues, or the scope of the Ninth Amendment in terms of those rights reserved to the people. Immunity provisions, interpreted broadly, tend to encourage bad behavior. There is no doubt that other circuits will look to this Third Circuit opinion, and eventually the matter may reach the halls of the United States Supreme Court.

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