STATE OF MICHIGAN
IN THE COURT OF APPEALS

MARK NOWACKI, as Legal Guardian and Conservator for DANIEL NOWACKI, and KATHLEEN P. NOWACKI,

Plaintiffs-Appellees,

v.

GILEAD SCIENCES, INC.,

Defendant-Appellant,

and

ST. JOSEPH MERCY CHELSEA, INC., *d/b/a* ST. JOSEPH MERCY CHELSEA,

Defendant.

Court of Appeals
Case No. 367271

Washtenaw County Circuit Court
Case No. 22-001761-N P

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BRIEF OF *AMICI CURIAE*
CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA AND THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA (PhRMA)

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INTEREST OF *AMICI CURIAE*[1]

The Chamber of Commerce of the United States of America is the world's largest business federation. It directly represents approximately 300,000 members and indirectly represents the interests of more than three million companies and professional organizations of every size, in every industry sector, and from every region of the country. An important function of the Chamber is to represent the interests of its members in matters before Congress, the Executive Branch, and the courts. To that end, the Chamber regularly files *amicus curiae* briefs in cases, like this one, that raise issues of concern to the nation's business community.

The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier and more productive lives. Over the last decade, PhRMA member companies have more than doubled their annual investment in the search for new treatments and cures, including nearly $101 billion in 2022 alone. PhRMA's mission is to advocate public policies that encourage the discovery of life-saving and life-enhancing medicines. PhRMA closely monitors legal issues that affect the pharmaceutical industry and frequently participates in such cases as an amicus curiae.

[1] Pursuant to MCR 7.312(H)(5), Amici Curiae state that no counsel for a party authored this brief in whole or in part, no such counsel or party made a monetary contribution intended to fund the preparation or submission of this brief, and no person other than Amici Curiae, their members, or their counsel made any such monetary contribution.

Accordingly, the Chamber and PhRMA have a strong interest in the proper interpretation and application of the federal Public Readiness and Emergency Preparedness (PREP) Act, 42 U.S.C. §§ 247d-6d, 247d-6e, which affords important protections, including immunity from most tort liability to those most critical to America's pandemic response: healthcare providers and pharmaceutical and medical device manufacturers and distributors.

INTRODUCTION AND SUMMARY OF ARGUMENT

The COVID-19 pandemic has tested the resilience of American business like nothing before. At the outset of the pandemic, business owners confronted a novel, fast-moving threat that no one, not even the nation's top public health experts, fully understood or anticipated. In responding to this emergency, businesses and health care providers had to adapt to rapidly changing circumstances and evolving guidance from public officials, often in the face of unprecedented restrictions on their operations.

And many, like Gilead, have risen to the challenge admirably. Gilead manufactures an antiviral drug, remdesivir, that is one of only a few FDA-approved treatments for the virus. Once remdesivir's potential to provide a viable treatment option became clear, Gilead doubled its manufacturing pace to meet the extraordinary demand. Although COVID has become less severe through treatments and immunity, Gilead and remdesivir were, and remain, a vital component of the national pandemic response.

The PREP Act incentivizes businesses like Gilead to do this work by protecting them from the risk of most litigation arising out of their cooperation in the nation's response to a health emergency. Specifically, the statute provides broad "immun[ity] from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure[.]" *Id.* § 247d-6d(a)(1). It carves out only claims involving willful misconduct causing death or serious injury for litigation in the U.S. District Court for the District of Columbia. For all other claims involving serious physical injury or death, an allegedly injured person can seek compensation from the federal government directly through a no-fault administrative compensation scheme. In essence, the government chose to act as an insurer: if a covered countermeasure causes a serious injury or death, the government compensates the affected patient, while at the same time protecting the people and entities that provided the countermeasure from a financial risk that could discourage their lifesaving work.

The decision below is not only inconsistent with the Act, it threatens the Act's very purpose. Congress knew that a public-private partnership would be needed to address national health emergencies, and the PREP Act was its tool for doing so. But the decision below threatens the immunity that enabled Gilead and other businesses to respond to the most recent pandemic, and it discourages them from doing similar work in future pandemics or national health emergencies.

The decisions that American businesses are making now—such as whether and how much to invest in research and development for pandemic countermeasures—will have a powerful impact on our national preparedness and emergency response for decades to come. Those businesses are watching this case, and others like it, to see if the PREP Act's promised protections will be enforced.

ARGUMENT

I. The PREP Act is intended to safeguard vital pandemic response activities now and in the future.

Congress enacted the PREP Act in 2005, just two years after the world narrowly escaped a global pandemic of the SARS virus. As Congress knew then, and the COVID-19 pandemic has brought into even sharper focus, America's healthcare system relies on a strong partnership between government and private industry. Robust private sector investment and innovation is what enables this country to produce the treatments and vaccines that can save so many lives, and to do so in record time. The PREP Act is designed to encourage that very private sector investment.

The recent pandemic highlighted how such private sector investment can save lives. April 2020 was a dark time for the entire world: COVID-19 had killed over 217,000 people and infected over 3.1 million, any vaccine was estimated to be at least a year away, and medical personnel had no effective treatments to fight the disease. When early clinical data demonstrated that Gilead's antiviral drug remdesivir was a safe and effective treatment for COVID-19, White House health

advisor Dr. Anthony Fauci hailed the "quite good news" and opined that remdesivir "will be the standard of care" for COVID-19 patients.[2] The U.S. Food and Drug Administration (FDA) reached out to Gilead directly in an effort to make remdesivir available to COVID-19 patients "as quickly as possible, as appropriate."[3]

Gilead stepped up to meet the urgent need, ramping up production and making "process improvements" that halved the manufacturing timeline, in pursuit of an ambitious goal to produce one million treatment courses by year-end.[4] Demand increased still further after National Institutes of Health (NIH) trials confirmed that remdesivir had "significant clinical benefits—faster recovery, shorter hospital stay, less need for mechanical ventilation and better survival—in patients hospitalized for COVID-19."[5]

Today, remdesivir remains one of only a small number of COVID-19 treatments to have received FDA approval.[6] It reduces a patient's risk of

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[2] Berkeley Lovelace Jr., *Dr. Anthony Fauci says Gilead's remdesivir will set a new 'standard of care' for coronavirus treatment*, CNBC.com (Apr. 29, 2020), https://www.cnbc.com/2020/04/29/dr-anthony-fauci-says-data-from-remdesivir-coronavirus-drug-trial-shows-quite-good-news.html.

[3] *Id.*

[4] Kyle Blankenship, *Gilead turbocharges production of COVID-19 hopeful remdesivir*, Fierce Pharma (Apr. 6, 2020), https://www.fiercepharma.com/manufacturing/gilead-to-donate-1-5m-doses-covid-19-hopeful-remdesivir-as-manufacturing-skyrockets.

[5] Julie Anderson, *Could earlier adoption of remdesivir have saved lives during the COVID pandemic?*, Omaha World-Herald (Apr. 11, 2023), https://omaha.com/news/local/could-earlier-adoption-of-remdesivir-have-saved-lives-during-the-covid-pandemic/article_41018154-b2f5-11ed-881f-7f9749bee06d.html.

[6] Kathy Katella, *COVID-19 Treatments: What We Know So Far*, Yale Medicine Family Health, https://www.yalemedicine.org/news/covid-19-treatment-drugs (May 26, 2023); *Coronavirus (COVID-19) Drugs*, FDA,

hospitalization and death by 87%.[7] It also shortened time to recovery, freeing up capacity for other COVID and non-COVID patients and protecting our medical infrastructure from being overwhelmed.[8] In short, Gilead's investment in remdesivir is the epitome of what the PREP Act sought to encourage.

While we can all hope that the worst of COVID-19 is behind us, that does not lessen the importance of the PREP Act or the public-private partnerships it encourages. A new viral threat could emerge at any time,[9] and experts anticipate that future pandemics may be even deadlier than COVID-19, which has killed nearly seven million people worldwide.[10] Vaccines for these potential superbugs do

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https://www.fda.gov/drugs/emergency-preparedness-drugs/coronavirus-covid-19-drugs#:~:text=Veklury%20(Remdesivir)%20is%20approved%20for,COVID%2D19%2C%20including%20hospitalization%20or.

[7] Robert L. Gottlieb, et al., *Early Remdesivir to Prevent Progression to Severe Covid-19 in Outpatients*, 386 N. Engl. J. Med. 305, 315 (Jan. 27, 2022).

[8] *Study Supports Use of Remdesivir for COVID-19 Patients on Low-Flow Oxygen or No Oxygen*, Johns Hopkins Medicine: Newsroom (Jan. 18, 2022), https://www.hopkinsmedicine.org/news/newsroom/news-releases/study-supports-use-of-remdesivir-for-covid-19-patients-on-low-flow-oxygen-or-no-oxygen.

[9] Catherine Adamson et al., *Antiviral drug discovery: preparing for the next pandemic*, 50 Chem. Soc. Rev. 3647, 3649 (Feb. 1, 2021), https://pubs.rsc.org/en/content/articlehtml/2021/cs/d0cs01118e.

[10] Aliza Chasan, *Prepare for next pandemic, future pathogens with 'even deadlier potential' than COVID, WHO chief warns*, CBS News (May 23, 2023), https://www.cbsnews.com/news/next-pandemic-threat-pathogen-deadlier-than-covid-world-health-organization/.

not yet exist,[11] and antiviral drugs will again be the first (and likely only) line of defense during the wait for a vaccine.[12]

Companies like Gilead can play a vital role in developing, producing, and deploying those lifesaving medications—but it is the PREP Act that Congress adopted to encourage such behavior. Unlike the public officials whom private companies may work alongside in response to an emergency, private companies may be subject to liability for negligence in their work. The PREP Act's targeted liability protections for companies engaged in some of the most critical work of our country's pandemic response are an antidote to that asymmetry. Those protections recognize and neutralize some of the significant risks for business that come from participating in a national pandemic response. Indeed, the lack of PREP Act-like protections in other countries has hindered the rollout of vaccines that could save untold numbers of lives.[13] As the Organization for Economic Cooperation and Development has observed, instituting "reliable and transparent legal provisions for the indemnification of vaccine manufacturers" is crucial for preventing a "wave of litigation" from "creating a disincentive for manufacturers to enter the vaccine

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[11] *World Has 28% Risk of New Covid-Like Pandemic Within 10 Years*, Bloomberg News (Apr. 13, 2023), https://www.bloomberg.com/news/articles/2023-04-14/another-covid-like-pandemic-could-hit-the-world-within-10-years#xj4y7vzkg.

[12] Gillian Rutherford, *New study shows why remdesivir works against SARS-CoV-2 but not on other viruses like the flu*, Univ. of Alberta Folio (Jan. 18, 2022), https://www.ualberta.ca/folio/2022/01/building-better-antivirals.html.

[13] *See, e.g.*, Neha Arora et al., *India, Pfizer Seek to Bridge Dispute Over Vaccine Indemnity*, Reuters (May 21, 2021), https://www.reuters.com/business/healthcare-pharmaceuticals/india-pfizer-impasse-over-vaccine-indemnity-demand-sources-2021-05-21/.

market."[14] Those reliable and transparent protections are precisely what the PREP Act is supposed to provide.

II. The decision below is contrary to both the text and purpose of the PREP Act.

The trial court's decision—that the PREP Act does not apply to claims for "negligent manufacture"—flies in the face of both the text of the immunity provision and its important public policy function. That decision is important to many businesses around the country, and it calls out for reversal by this Court.

A. The PREP Act expressly grants immunity against claims regarding "manufacture" of a "covered countermeasure" like remdesivir.

The text of the PREP Act's immunity provision is broad. It provides: "a covered person shall be immune from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure[.]" 42 U.S.C. § 247d-6d(a)(1). The PREP Act further specifies that this immunity applies to "*any* claim for loss that has a causal relationship with the administration to or use by an individual of a covered countermeasure, including" with "the design, development, clinical testing or investigation, ***manufacture***, labeling, distribution, formulation, packaging, marketing, promotion, sale,

[14] *Enhancing Public Trust in COVID-19 Vaccination: The Role of Governments*, OECD (May 10, 2021), https://www.oecd.org/coronavirus/policy-responses/enhancing-public-trust-in-covid-19-vaccination-the-role-of-governments-eae0ec5a/.

purchase, donation, dispensing, prescribing, administration, licensing, or use of such countermeasure." *Id.* § 247d-6d(a)(2)(B) (emphasis added).

The decision at issue in this case flies in the face of the statutory text. *See Pohutski v City of Allen Park*, 465 Mich 675, 683 (2002) (explaining that any judicial interpretation of a statute must begin with the text). There is no dispute that Gilead, as "a manufacturer of such countermeasure," is a "covered person." 42 U.S.C. § 247d-6d(i)(2). Nor do the plaintiffs contend that remdesivir itself is not a "covered countermeasure[.]" *Id.* § 247d-6d(i)(1). Instead, Plaintiffs argue that because of the alleged adulteration of remdesivir with glass particles, it was no longer a "covered countermeasure." Yet plaintiffs' argument, which the trial court adopted, would effectively read the word "manufacture" out of the statute. A manufacturing defect by its nature means that there will be some disparity between the approved product and the actual product. But the Act expressly extends immunity to claims related to "manufacture" of a covered countermeasure. *Id.* § 247d-6d(a)(2)(B). It is hard to imagine what Congress could possibly have intended that word to cover if not these types of circumstances. Moreover, the laundry list of different activities within the scope of the immunity only confirms its breadth.

Thus, as the federal district court for the Eastern District of Michigan recognized, "[t]his argument is unsupported by any authority and contrary to the plain text of the PREP Act. The Act's broad grant of immunity from suit and liability with respect to all claims relating to the administration to or use of a

covered countermeasure makes clear that a product's alleged departure from FDA-approved manufacturing specifications does not remove it from the Act's protection." Gilead App. 079–080.

Consistent with the Act's plain language, the Secretary of Health and Human Services (HHS) has specifically cited a manufacturing defect as an example of a claim for which the PREP Act grants immunity: "it is the Secretary's interpretation that, when a Declaration is in effect, the Act precludes, for example, liability claims alleging negligence by a manufacturer in creating a vaccine . . . ." Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15198-01 (Mar. 17, 2020).

Because Plaintiffs' contention that the PREP Act permits claims for negligent manufacture of covered countermeasures is directly contrary to the text itself, it must be rejected.

B. This Court's review is needed to ensure that the PREP Act is able to protect businesses as Congress intended.

The error at issue here is no mine run error; it implicates an important statute that is being litigated around the country. Indeed, trial lawyers have already spent tens of millions of dollars on advertisements related to COVID-19, and more than 8,200 lawsuits have already been filed, in every state across the country.[15] If the trial court's reading were to spread, manufacturers of every kind of

[15] Am. Tort Reform Ass'n, *COVID-19 Legal Services Television Advertising (2021)*, https://www.atra.org/white_paper/covid-19-legal-services-television-advertising/.

covered countermeasure—such as vaccines, antiviral drugs, masks, and sanitizers, to name only a few—would be vulnerable to product liability claims that should have been handled through the administrative compensation process. These claims will seriously deter businesses from the conduct the PREP Act is meant to encourage and could even cripple or destroy smaller businesses that had reasonably relied on the PREP Act's guarantees of immunity from suit and liability. That is neither what Congress intended nor what the law requires.

By passing the PREP Act, Congress intended to strengthen America's "manufacturing capacity" to produce vaccines, antivirals, and other pandemic countermeasures. 151 Cong. Rec. H12244-03, H12264, 2005 WL 3466298 (Dec. 18, 2005) (statement of Rep. Nathan Deal). Congress understood that manufacturers would not be able to "take on the tremendous liability risks to produce" those products without liability protections, *id.*, and that government would be unable to muster an adequate pandemic response without the partnership of private industry. Statement of Interest of the United States at 2, ECF No. 35-1, *Bolton v Gallatin Ctr for Rehab & Healing, LLC*, Case No 20-cv-00683 (M.D. Tenn. Jan 19, 2021) (noting that "[s]uccessful distribution and administration of [pandemic] countermeasures . . . depends on the cooperation of private-sector partners" and that the PREP Act was intended "[t]o encourage such cooperation and to maximize the efficiency of the national response to public health emergencies").

Notably, the PREP Act immunizes covered entities *from suit* as well as *from liability*, ensuring that they will not be bogged down in costly litigation that will

ultimately fail. 42 U.S.C. § 247d-6d(a)(1) ("a covered person shall be immune from ***suit and liability*** under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure[.]" (emphasis added)). Congress's purpose in enacting the Act is thwarted where immunized claims reach discovery and divert covered entities' resources toward litigation costs.

In this case, the trial court denied Gilead's motion to dismiss *and* its motion to stay its ruling pending appeal, effectively stripping Gilead of its immunity from suit and subjecting it to one of the very burdens that Congress intended to shield it from: the burden of discovery. To protect its entitlement to immunity from suit, Gilead has filed another motion for stay in this Court. If that motion is not soon granted, Gilead will effectively lose its immunity from suit and be forced to litigate this case—again, the opposite of what Congress intended for a business engaged in pandemic response. Thus, although the PREP Act was designed, "in part, to remove legal uncertainty and risk" for businesses and individuals engaged in critical pandemic response efforts, Advisory Opinion No. 20-04 on the PREP Act, 1 (HHS OGC Oct. 22, 2020), as modified (Oct. 23, 2020), the decision below revives all that uncertainty and risk.

This Court should step in now. The trial court's decision is contrary to what Congress said and to what Congress meant, and it will not make anyone safer from COVID-19 or the next pandemic. The decision below should be reversed.

CONCLUSION

The Court should grant the application for leave to appeal, reverse the trial court's decision, and remand with instructions to dismiss Plaintiffs' complaint with prejudice as barred by the PREP Act.

Respectfully submitted,

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WORD COUNT CERTIFICATION

I hereby certify that, according to the word-count feature of Microsoft Word used to prepare this brief, this brief contains 2,937 words in the sections covered by MCR 7.212(C)(6)–(8).

/s/ Aaron D. Lindstrom