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

Nearly 15 years before the COVID-19 pandemic struck, the United States Congress enacted the PREP Act "to address the threat of pandemic flu and other bioterror threats." 151 Cong. Rec. H12244-03, H12264, 2005 WL 3466298 (Dec. 18, 2005) (statement of Rep. Nathan Deal). The legislators made their goal clear: "So why are we passing this legislation? It's simple. We cannot afford not to take the important steps of making sure we can get and deliver a vaccine" and other lifesaving medications to fight a deadly pathogen. *Id.* In other words, Congress feared that if a pandemic occurred, "manufacturers" would not "take on the tremendous liability risks" to produce medications and vaccines, and the entire burden of addressing the crisis would fall on a federal government unable to shoulder it alone. *Id.* Rather, Congress saw it necessary to harness the power of the private sector to work alongside the government to respond to public health crises.

To facilitate this outcome, Congress empowered the Secretary of Health and Human Services, in the event of a pandemic emergency, "to declare limited liability protection" for manufacturers and thus to incentivize vaccine and pharmaceutical

development and production. *Id.* Specifically, the Secretary can declare 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," including claims related to the countermeasure's "manufacture[.]" 42 U.S.C. § 247d-6d(a)(1), (2)(B). Congress wanted to "provide the authority and be prepared, so that the Secretary and any Congress faced with the real deal can act quickly and responsibly." 151 Cong. Rec. H12244-03, H12264, 2005 WL 3466298 (Dec. 18, 2005) (statement of Rep. Nathan Deal).

The "real deal" came soon enough. On March 11, 2020, the World Health Organization declared that COVID-19, which had already killed over 4,000 people and sickened 118,000 more, was a global pandemic.[2] The WHO warned that healthcare providers were seeing "alarming levels of spread and severity" and that it expected soon "to see the number of cases, the number of deaths, and the number of affected countries climb even higher."[3] To address this looming catastrophe, the WHO called on the global community to "innovate and learn" and "activate and

[2] WHO Director-General's opening remarks at the media briefing on COVID-19 (Mar. 11, 2020), World Health Organization, https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020.

[3] *Id.*

scale up . . . emergency response mechanisms" to "prevent infections, save lives and minimize impact" on the economy and society.[4]

American businesses answered that call. In an industry publication identifying "[t]he top 10 manufacturers in the fight against COVID-19," eight were either American or working in partnerships with American businesses.[5] Indeed, American companies, including Michigan companies, of all sizes contributed to the response effort. The appellant here, Gilead, played a particularly significant role by manufacturing one of only a few FDA-approved treatments for the virus: the antiviral drug remdesivir. In the early days of the pandemic, Gilead realized remdesivir's potential as a treatment option and doubled its manufacturing pace to meet the extraordinary demand. Three years later, Gilead and remdesivir remain important components of the continuing national pandemic response effort, particularly for seniors and other high-risk patients.[6]

As Congress recognized, without the PREP Act, the specter of liability would have discouraged Gilead and countless other similarly situated businesses from investing in vital manufacturing work that saved so many lives during the COVID-19 pandemic. Both the statute's purpose and text demonstrate that it is intended to

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[4] *Id.*

[5] Kyle Blankenship, "The top 10 manufacturers in the fight against COVID-19," FiercePharma (Dec. 8, 2020), https://www.fiercepharma.com/special-report/top-10-manufacturers-fight-against-covid-19.

[6] John Parkinson, "Remdesivir Shows Reduction in Mortality in Seniors Hospitalized With COVID-19," ContagionLive (Apr. 29, 2024), https://www.contagionlive.com/view/remdesivir-shows-reduction-in-mortality-in-seniors-hospitalized-with-covid-19.

apply to the appellees' claims for negligent "manufacture" of remdesivir, a "covered countermeasure." This Court should fulfill Congress' purpose by reversing and holding that appellees' claims are preempted.

ARGUMENT

I. The statutory text and structure demonstrate that the PREP Act applies to claims for "negligent manufacture."

Both the plain text and the broad structure of the PREP Act demonstrate that it applies to the appellees' claims. A contrary result would be both illogical and inconsistent with plaintiff's own concessions that Gilead is a covered person under the statute.

A. The appellees' claims "relate to" the "manufacture" of a covered countermeasure and therefore fall within the scope of the immunity provision.

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) (emphasis added). 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, purchase, donation, dispensing,

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

Any judicial interpretation of the statute must begin with this statutory text. *See Pohutski v City of Allen Park*, 465 Mich. 675, 683 (2002). As the federal Supreme Court has repeatedly recognized, the term "relat[ing] to" has a "broad common-sense meaning." *Pilot Life Ins. Co. v. Dedeaux*, 481 U.S. 41, 47 (1987) (internal quotation marks omitted); *see also Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 383 (1992) ("the ordinary meaning of ['relating to'] is a broad one."). In that vein, as the Secretary explained in invoking the PREP Act here, even allegations of "failure" to use a countermeasure may "relat[e] to . . . the administration to or the use" of a covered countermeasure. The Secretary's declaration designating covered countermeasures for diagnosing, preventing, and treating COVID-19 expressly adopted the plain-meaning interpretation of "administration" of a countermeasure to include not only "physical provision" of the countermeasure, but also "decisions directly relating to public and private delivery, distribution, and dispensing" of the countermeasure, as occurs in the context of a health care provider's administration of an infection control policy directed at controlling the spread of COVID-19. Declaration Under the PREP Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15,198, 15,200 (Mar. 17, 2020).

Likewise, the statutory grant of immunity expressly applies to claims arising out of the "manufacture" of a covered countermeasure, which appellees made the explicit basis of each of the relevant claims:

- Count I: "[T]he Remdesivir drug administered to Dan . . . was not in accordance [with] Gilead's FDA approval for the drug in terms of its ***manufacturing quality*** . . . as it [allegedly] contained glass particles (foreign body)." Appellant's App'x at 15a (Compl. ¶ 45) (emphasis added);

- Count II: "Gilead breached these express warranties by . . . ***manufacturing*** . . . defective and unreasonably dangerous Remdesivir drug [allegedly] containing glass particles[.]" *Id.* at 17a (Compl. ¶ 51) (emphasis added);

- Count III: "***Gilead was negligent in . . . manufacture*** . . . of the Remdesivir drug at the time it left Gilead's control[.]" *Id.* at 18a (Compl. ¶ 58) (emphasis added); and

- Counts IV and V: "Gilead owed the general public including[] Dan a duty to appropriately . . . ***manufacture*** . . . Remdesivir drug free from glass particles (foreign body)." *Id.* at 20a, 22a (Compl. ¶¶ 61, 67) (emphasis added).

Applying the plain text of the PREP Act to the appellees' claims is simple: because the appellees' claims "relate to" the "manufacture" of a covered countermeasure, they fall within the scope of the PREP Act's immunity provision.

The appellees have tried to evade the plain statutory text by suggesting that because "the parties have not [yet] engaged in any discovery[,]" it would be "premature[ ]" for the "Court to conclude that the glass particles . . . resulted from the manufacturing process." Appellees' Resp. Br. to St. Joseph Mercy Chelsea's Br. on Appeal at 18. But as the above bullets demonstrate, that is exactly what the appellees are alleging: that Gilead failed "to appropriately . . . ***manufacture*** . . . Remdesivir drug free from glass particles (foreign body)." Appellant's App'x at 20a, 22a (Compl. ¶¶ 61, 67) (emphasis added). At the summary-disposition stage, the Court must take the appellees' "well-pleaded factual allegations . . . as true[.]" *Doe v. Gen. Motors, LLC*, 511 Mich. 1038, 1039 (2023) (quoting *Maiden v Rozwood*, 461

Mich. 109, 119 (1999)). Appellees cannot on appeal escape their choice to plead claims of negligent manufacture. And in any event, the allegations' precise contours and ultimate merit are irrelevant; because the claims, under any interpretation, "relate to" the "manufacture" of a covered countermeasure, they are barred by the immunity provision of the PREP Act and must be dismissed.

B. The appellees' contention that the allegedly contaminated remdesivir is not a "covered countermeasure" is both illogical and atextual.

The appellees have conceded that Gilead is a "covered person" under the statute, 42 U.S.C. § 247d-6d(i)(2)(B)(i), and that remdesivir is generally a "covered countermeasure," *id.* § 247d-6d(i)(1), but they assert that the specific remdesivir at issue in this case—the allegedly contaminated remdesivir—is not a "covered countermeasure." Appellees' Resp. Br. to Gilead's Br. on Appeal at 21 ("Defendant can establish that it is a covered person") Appellees' Resp. Br. to St. Joseph Mercy Chelsea's Br. on Appeal at 19 (same). In essence, the appellees contend that the alleged presence of a contaminant changed the remdesivir into some other substance to which the PREP Act does not apply, suggesting that the Court "must look at each remdesivir unit as a standalone to determine whether the drug administered to the patient was administered in the form that FDA approved." Appellees' Resp. Br. to Gilead's Br. on Appeal at 17; Appellees' Resp. Br. to St. Joseph Mercy Chelsea's Br. on Appeal at 16.

This faulty logic finds no purchase in any other area of the law. No reasonable lawyer could argue, for example, that an alleged manufacturing defect in

a bicycle somehow transmogrifies the bicycle into some other product not subject to the federal Requirements for Bicycles, 16 C.F.R. part 1512. A defective bike is still a bike. And no one would think, in the context of product-liability insurance, that a defective product is not a product; applying the appellees' reasoning in that context would mean that the coverage would be illusory, since any defect in the product would mean the product was no longer covered. *See Home Warranty Corp. v. Caldwell*, 777 F.2d 1455, 1486 (11th Cir. 1985) ("product liability insurance seeks to distribute a product manufacturer's or seller's risk that he will be held liable for damages that his product will, *through defect*, cause to another.") (emphasis added).

This common-sense principle is perhaps most saliently illustrated in the context of cases involving allegedly adulterated food. For example, in *United States v. S. Serra Cheese Co.*, the FDA brought an enforcement action against a cheesemaker for allegedly distributing "adulterated" cheese. The cheesemaker argued that the cheese itself was not contaminated, but rather certain ingredients added to the cheese during the manufacturing process were the source of the alleged contamination. The court rejected this artificial distinction, reasoning that "[c]ontaminants in a finished product produce a contaminated product—whether the contamination is from the cheese or the added ingredients." No. 14-13077, 2015 WL 6156961, at *6 (E.D. Mich. Oct. 20, 2015). In other words, contaminated cheese is still cheese—a manufacturer can no more escape liability by claiming that a defect changes a product's nature than a plaintiff can escape immunity through the same flawed argument.

The same is true here: allegedly contaminated remdesivir is still remdesivir, and therefore still a "covered countermeasure." If that were not so, there would be no need to grant immunity from claims related to the manufacture of the covered countermeasure, because only perfectly manufactured products would be covered countermeasures. In short, if a contaminated countermeasure were not still a countermeasure, the statute would be ineffectual at best and nonsensical at worst.

And there is another flaw in the appellees' logic. If the allegedly contaminated remdesivir were not a "covered countermeasure," Gilead would not be a "covered person," which is defined as "a person or entity that is . . . a manufacturer of [a covered] countermeasure[.]" 42 U.S.C. § 247d-6d(i)(2)(B)(i). Yet even the appellees do not dispute that Gilead is a "covered person." Appellant's App'x at 492a (Order Remanding Claims to State Court at 15); *id.* at 822a. The fact that even the appellees cannot apply their own logic across the entirety of the statute should invite this Court to reject it in full.

Further, applying the appellees' reasoning to other activities enumerated in the PREP Act would render even more of the statutory text meaningless. The grant of immunity extends "to any claim for loss that has a causal relationship with the administration to or use by an individual of a covered countermeasure, including a causal relationship with 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." 42 U.S.C. § 247d-6d(a)(2)(B) (emphasis

added). If an alleged *manufacturing* defect truly rendered a product not a "covered countermeasure," that would seem also to mean that an alleged *labeling* defect would similarly render the product not a "covered countermeasure." Likewise with respect to alleged "distribution, formulation, packaging, marketing, [or] promotion" defects—distributing remdesivir to the wrong hospital, packaging it in a faulty container, or advertising it inaccurately, would all render it no longer a "covered countermeasure." Indeed, under such an interpretation, it is not clear what sort of allegation a plaintiff could make regarding a product that would ***not*** remove it from the scope of "covered countermeasures."

Further, the appellees' reasoning would have another perverse effect on the balanced scheme Congress enacted: if the allegedly contaminated remdesivir were not a "covered countermeasure," then the appellees could not avail themselves of the PREP Act's administrative compensation program, which is available only for injuries "caused by the administration or use of a covered countermeasure[.]" 42 U.S.C. § 247d-6e(b)(1); *accord* Appellees' Resp. Br. to St. Joseph Mercy Chelsea's Br. on Appeal at 21 ("To be eligible to receive compensation, the claimant is required to produce documentation that a covered injury was sustained as a direct result of the administration or use *of a covered countermeasure* pursuant to the terms of the HHS declaration.") (emphasis added).

The Secretary does not subscribe to the appellees' view, and indeed specifically cited a manufacturing defect as an example of a claim for which the PREP Act ***does*** grant 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, 15,200 (Mar. 17, 2020).

In short, as the federal district court for the Eastern District of Michigan recognized in this very case, the appellees' "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." Appellant's App'x. at 495a (Order Remanding Claims to State Court at 18, *Nowacki v. Gilead Sciences, Inc., et al.*, No. 2:23-cv-10276-VAR-CI (June 13, 2023) (internal citation omitted)).

II. Vitiating the PREP Act's statutory protections thwarts Congress's intent and leaves America more vulnerable to the next pandemic.

The appellees' proposed interpretation of the statutory text would defeat the important purpose for which Congress enacted it: to ensure that, in the event of a pandemic, American businesses will step up and deliver life-saving vaccines and medications.

A. Congress intended to protect critical pandemic-response businesses from most suits and liability.

Notwithstanding that purpose and the plain statutory test effectuating it, the trial court in this case adopted the appellees' view: "I can't find that [Congress] intended to insulate a company from its negligence in placing contaminants, or allowing contaminants to be distributed with the product." Appellant's App'x 800a. In fact, as the statutory structure shows, Congress intended *precisely* that. The PREP Act immunizes covered persons from claims for "negligence," and it creates instead a general federal administrative claims process, alongside a federal cause of action for claims of willful misconduct. 42 U.S.C. § 247d-6d(c)(1)(A), (B). That cause of action "establish[es] a standard for liability that is more stringent than a standard of negligence in any form or recklessness," *id.* By expressly creating a cause of action for only willful misconduct, Congress indicated that it intended completely to preempt claims for ordinary negligence (and indeed even recklessness). Indeed, even a claim for "willful misconduct" is defensible if the manufacturer initiates a voluntary recall of the product at issue, *see* 42 USC § 247d–6d(c)(5)(A)(i), and typically, manufacturers recall products due to actual or suspected manufacturing defects, such as contamination. As this statutory structure demonstrates, Congress had exactly this type of litigation in mind when it enacted the PREP Act.

Moreover, Congress intended to—and did—immunize covered entities from *suit* as well as from *liability*, protecting them from the mire of fruitless and costly litigation. 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)). That intent is thwarted when immunized claims persist into discovery, as appellees here request, squandering covered entities' resources on litigation costs.

B. The PREP Act's immunity provision must be upheld to ensure that businesses will be willing and able to help America fight the next pandemic.

When the COVID-19 pandemic struck, the PREP Act worked exactly as Congress intended. The Secretary exercised his authority to make the declaration of immunity. American industry, secure in that safeguard, developed, manufactured, and delivered millions of doses of lifesaving vaccines and pharmaceuticals in record time.

We may not know whether the next pandemic will come in the form of a bird flu,[7] a paramyxovirus,[8] or even an AI-generated pathogen,[9] but come it will: "the next pandemic is a matter of when, not if."[10] As they did during the COVID-19

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[7] Jamie Hansen, "Could the avian flu be our next pandemic threat?" Scope (May 14, 2024), https://scopeblog.stanford.edu/2024/05/14/bird-avian-flu-h5n1-cows-pandemic-threat/.

[8] Katherine J. Wu, "The Viral Threat Almost No One Is Thinking About," The Atlantic (Oct. 29, 2023), https://www.theatlantic.com/science/archive/2023/10/paramyxovirus-next-pandemic-flu-covid/675785/.

[9] Ryan Heath, "Another AI threat: The next pandemic," Axios (June 16, 2023), https://www.axios.com/2023/06/16/pandemic-bioterror-ai-chatgpt-bioattacks.

[10] WHO Director-General's speech at the World Governments Summit (Feb. 12, 2024), World Health Organization, https://www.who.int/director-

pandemic, federal, state, and local governments will rely on American businesses to take the lead in the production of countermeasures. 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"). Antiviral drugs like remdesivir could be a vital component of the overall response, but without the protections of the PREP Act, the number of companies willing to take the risk to develop and manufacture such drugs[11] will shrink.

Congress knew that a national health emergency would require a strong public-private partnership, and it enabled that partnership through the PREP Act. But now, plaintiffs in Michigan and in other jurisdictions ask courts to chip away at the liability shield that made that vital work possible. The appellees in this case are inviting this Court to shatter the shield entirely; if the Act's immunity does not apply to this textbook scenario of allegedly negligent manufacture of a covered countermeasure, it is unclear when it would ever apply. That result would dramatically increase the risks for businesses asked to help the government respond to national health emergencies. And when businesses must weigh those

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general/speeches/detail/who-director-general-s-speech-at-the-world-governments-summit---12-february-2024.

[11] *See* "In the Next Pandemic Antiviral Drugs Could be Key, But Are They Ready?" WatchBlog: Following the Federal Dollar, U.S. Gov't Accountability Office (Oct. 4, 2023), https://www.gao.gov/blog/next-pandemic-antiviral-drugs-could-be-key-are-they-ready.

risks in the future, the PREP Act's continued viability may determine whether American business can step up again—or not.

CONCLUSION

The Court should 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 3,784 words in the sections covered by MCR 7.212(C)(6)–(8).

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CERTIFICATE OF SERVICE

I hereby certify that on August 22, 2024, I caused the foregoing paper to be electronically served on all counsel of record via the MiFILE system.

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