UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

ABBVIE INC., *et al.*, *Plaintiffs*, *v.* KEITH M. ELLISON, in his official capacity as ATTORNEY GENERAL OF THE STATE OF MINNESOTA, *Defendant*.	Case No. 0:24-cv-02605-DSD-TNL

BRIEF OF *AMICI CURIAE* AMERICAN HOSPITAL ASSOCIATION, 340B HEALTH, MINNESOTA HOSPITAL ASSOCIATION, AND AMERICAN SOCIETY OF HEALTH-SYSTEM PHARMACISTS IN SUPPORT OF DEFENDANT'S MOTION TO DISMISS

David W. Asp (Bar No. 344850)
Derek C. Waller (Bar No. 0401120)
LOCKRIDGE GRINDAL NAUEN PLLP
100 Washington Avenue S, Suite 2200
Minneapolis, MN 55401
Tel: (612) 339-6900
Fax: (612) 339-0981
dwasp@locklaw.com
dcwaller@locklaw.com

Counsel of Record
Counsel for Amici Curiae

William B. Schultz*
Margaret M. Dotzel*
Alyssa Howard Card*
ZUCKERMAN SPAEDER LLP
1800 M Street NW, Suite 1000
Washington, DC 20036
Tel: (202) 778-1800
Fax: (202) 822-8106
wschultz@zuckerman.com
mdotzel@zuckerman.com
acard@zuckerman.com
* *pro hac vice* motion forthcoming

Counsel for Amici Curiae

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INTERESTS OF *AMICI CURIAE*

Amici are non-profit organizations whose members receive 340B discounts for drugs that they purchase, many of which are dispensed through contract pharmacies. *Amici* and their members are committed to improving the health of the communities they serve. The discounts provided by the 340B program are essential to achieving this goal. *Amici* therefore have a strong interest in the success of Minnesota legislative efforts to protect the 340B program.

The **American Hospital Association** (AHA) represents nearly 5,000 hospitals, healthcare systems, and other healthcare organizations nationwide. AHA members are committed to helping ensure that healthcare is available to and affordable for all Americans. AHA promotes the interests of its members by participating as *amicus curiae* in cases with important and far-ranging consequences for their members, including cases related to the 340B program.

340B Health is a national, not-for-profit organization founded in 1993 to advocate for 340B hospitals—a vital part of the nation's healthcare safety net. 340B Health represents over 1,500 public and private nonprofit hospitals and health systems participating in the 340B program.

The **Minnesota Hospital Association** (MHA) is an organization representing non-profit hospitals and health systems across the state to advance the health of individuals and communities through leadership, advocacy, and collaboration. Over 100 MHA members participate in the 340B program.

The **American Society of Health-System Pharmacists** (ASHP) is the largest association of pharmacy professionals in the United States. ASHP advocates and supports the professional practice of pharmacists in hospitals, health systems, ambulatory care clinics, and other settings spanning the full spectrum of medication use. For over 80 years, ASHP has championed innovation in pharmacy practice; advanced education and professional development; and served as a steadfast advocate for members and patients.

BACKGROUND AND SUMMARY OF ARGUMENT

Four years ago, amid a devastating pandemic, multiple drug companies broke with decades of precedent and began to undermine the 340B drug discount program. Under that program, drug companies that participate in Medicaid and Medicare Part B must provide discounts on drugs sold to patients of certain nonprofit or public hospitals and community health centers. *See* 42 U.S.C. § 256b(a)(1)–(4). Before 2020, drug companies had provided drug pricing discounts to eligible 340B providers for drugs dispensed *both* through in-house pharmacies and community pharmacies with which the providers had contracts. *See PhRMA v. McClain*, 95 F.4th 1136, 1139 (8th Cir. 2024) ("For 25 years, drug manufacturers . . . distributed 340B drugs to covered entities' contract pharmacies."). But in July 2020, one drug company made an about-face and refused to provide these discounts for drugs if dispensed to 340B patients at community pharmacies (or contract pharmacies).[1] Recognizing an opportunity to boost its own bottom line, Plaintiff AbbVie, Inc.

[1] *See* Maya Goldman, *Hospital Groups Worry As More Drugmakers Limit 340B Discounts*, Modern Healthcare (Mar. 25, 2022), https://www.modernhealthcare.com/safety-net-hospitals/hospitals-worry-more-drugmakers-limit-340b-discounts.

(collectively with the other Plaintiffs, AbbVie) and 36 other major drug companies followed suit.[2]

The contract pharmacy arrangements that drug companies honored for almost 30 years helped sustain 340B providers and their patients. Prior to the implementation of contract pharmacy restrictions, discounts on drugs dispensed at community and specialty contract pharmacies made up about one-quarter of overall 340B savings for hospitals participating in 340B. Of the 104 Minnesota hospitals participating in the 340B drug program, 92 contract with at least one community pharmacy to dispense drugs to patients.[3] The drug company restrictions have substantially cut the savings from the 340B program, which is devasting for hospitals in Minnesota that provide 88% of all hospital care that is provided to Medicaid patients.[4]

For example, 340B savings allow Fairview Health Services, a health system headquartered in Minneapolis, to provide critical care to patients throughout the metropolitan area at three Health Commons locations in economically and culturally diverse neighborhoods. The Health Commons locations are responsible for almost 11,000

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[2] Collectively, 19 of these companies made more than $660 billion in profits in 2021. *See* 340B Informed, *Drugmakers Cutting 340B Discounts Reported Record Revenues in 2021* (updated Jan. 13, 2023), https://340binformed.org/2023/01/updated-drugmakers-cutting-340b-discounts-reported-record-revenues-in-2021/.

[3] Health Res. & Servs. Admin, Off. of Pharmacy Affairs, *340B OPA Info. Sys.*, https://340bopais.hrsa.gov/coveredentitysearch (last visited Aug. 5, 2024).

[4] Dobson DaVanzo Health Economics Consulting, *Minnesota 340B Hospitals Serve More Patients With Low Incomes, Who Live With Disabilities, and/or Identify as Black* 1, https://www.340bhealth.org/files/MN-340B-Low-Income15021.pdf (last visited Aug. 5, 2024).

patient visits annually and provide health education through an onsite community nurse, offer wellness classes, and distribute free meals, fresh produce, diapers, and more to those in need. The Cedar Riverside Health Commons location has also begun providing naloxone training and has been designated a Naloxone Access Point.

A rural health system headquartered in Duluth, Essentia Health (Essentia) has 14 hospitals throughout Minnesota, North Dakota, and Wisconsin, which care for a service area that is classified as 84% rural. All of these hospitals, including seven critical access hospitals in Minnesota, are 340B covered entities that leverage 340B savings to ensure the rural and underserved communities they serve have access to comprehensive, local health care services, such as 24/7 emergency care, intensive care, mental and behavioral health services, and primary and specialty care. As a rural safety-net hospital system that cares for some of the State's most vulnerable patients, Essentia relies heavily upon the 340B program to offset chronically low Medicaid and Medicare reimbursement rates that have been outpaced by the current costs of care. In 2023, underpayments from Medicaid and Medicare payments exceeded $368 million—far exceeding the $149 million Essentia saved through the 340B program.

Winona Health, an independent, rural hospital in Winona, Minnesota, has likewise been hit hard by increased drug costs resulting from manufacturers' restrictive contract pharmacy policies. At the end of June 2024, 340B revenues were down by $2.2 million (or 65.2%), and overall drug costs were up $1.05 million (or 12.8%). Winona Health uses 340B savings to subsidize programs that don't generate revenue, and the hospital has had to dip into investments to pay operating costs and cut back on capital investments as a

result of these losses. For example, Winona Health recently almost had to close its dialysis department. Although private donations have saved the dialysis program for the next three years, severe financial challenges remain, and they will be compounded if Minnesota's statute is invalidated.

Contract pharmacy arrangements are especially important because fewer than half of 340B hospitals operate in-house pharmacies.[5] This is why 340B hospitals have relied on contract pharmacies since the beginning of the program.[6] In addition, the restrictive drug manufacturer policies do not recognize that payors and pharmacy benefit managers (PBMs) influence where patients must fill their prescriptions. For example, many payors require that certain specialty drugs be filled only at a PBM-owned "specialty pharmacy." Such "specialty" drugs are typically used to treat chronic, serious, or life-threatening conditions, and are often priced much higher than non-specialty drugs.[7] Only one in five 340B hospitals have in-house "specialty" pharmacies. Thus, 340B hospitals typically *must* contract with at least one specialty pharmacy to receive the 340B discount for their

[5] 340B Health, *Drugmakers Pulling $8 Billion Out of Safety-Net Hospitals: More Expected as Growing Number Impose or Tighten 340B Restrictions* (July 2023), https://www.340bhealth.org/files/Contract_Pharmacy_Financial_Impact_Report_July_2023.pdf.

[6] *See* Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Contracted Pharmacy Services, 60 Fed. Reg. 55,586 (Nov. 1, 1995).

[7] Adam J. Fein, *Insurers + PBMs + Specialty Pharmacies + Providers: Will Vertical Consolidation Disrupt Drug Channels in 2020?*, Drug Channels Institute (Dec. 12, 2019), https://www.drugchannels.net/2020/05/insurers-pbms-specialty-pharmacies.html; U.S. Dep't of Health & Hum. Servs. Off. Of Inspector Gen., *Specialty Drug Coverage and Reimbursement in Medicaid*, https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000255.asp (last visited Aug. 5, 2024).

patients' high-priced specialty drugs.[8] In fact, for seven of the 21 drug companies with restrictive contract pharmacy policies as of June 1, 2023, specialty drugs make up more than three-quarters of the savings associated with restricted drugs.[9]

If patients are unable to afford prescriptions or have other barriers to filling prescriptions, such as having to travel long distances to obtain a discount on a prescription drug, they are more likely to forgo treatment and fall out of compliance with prescription drug regimens. This can lead to hospital readmission or avoidable emergency department visits,[10] increasing the overall cost of care for the patient, the hospital, and the health care system.

Savings from contract pharmacy relationships are especially important for another reason: the fragile state of 340B hospital finances. In stark contrast to the pharmaceutical industry, 340B hospitals typically operate with razor-thin (and often negative) margins.[11] This is not surprising: 340B hospitals provide a disproportionate amount of uncompensated

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[8] 340B Health, *supra* note 4, at 7 (citing Fein, *supra* note 6).

[9] 340B Health, *supra* note 4, at 6.

[10] Holly C. Felix, et al., *Why Do Patients Keep Coming Back? Results of a Readmitted Patient Survey,* 54 SOC. WORK HEALTH CARE 1, 7 (2015).

[11] AHA, *340B Drug Pricing Program: Fact vs. Fiction* 2 (Apr. 2023), https://www.aha.org/system/files/2018-04/340BFactvsFiction.pdf; Allen Dobson *et al.*, *The Role of 340B Hospitals in Serving Medicaid and Low-income Medicare Patients* 12–13 (July 10, 2020), https://www.340bhealth.org/files/340B_and_Medicaid_and_Low_Income_Medicare_Patients_Report_7.10.2020_FINAL_.pdf.

care to the country's most vulnerable patients.[12] Savings from the 340B program help to offset the cost of providing uncompensated health care. As the Supreme Court recognized, "340B hospitals perform valuable services for low-income and rural communities but have to rely on limited federal funding for support." *AHA v. Becerra*, 596 U.S. 724, 738 (2022).

In late May 2024, the Minnesota legislature acted to address the drug industry's unprecedented assault on its health care safety net. Codified at Minnesota Statutes section 62J.96,[13] the relevant provision does not allow a manufacturer to "directly or indirectly restrict, prohibit, or otherwise interfere with the delivery of a covered outpatient drug to a pharmacy that is under contract with a 340B entity to receive and dispense covered outpatient drugs on behalf of the covered entity[.]" Minn. Stat. § 62J.96, subds 1, 3 (2024).[14]

AbbVie now seeks to halt Minnesota's lawful exercise of its police power to protect public health and safety. AbbVie's amended complaint should be dismissed because it fails to state a claim for relief. *First*, AbbVie's preemption claim is squarely foreclosed by *PhRMA v. McClain*. The Eighth Circuit has already held that Congress did not create or

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[12] *See* L&M Policy Research, LLC, *Analysis of 340B Disproportionate Share Hospital Services to Low-Income Patients* 1 (Mar. 12, 2018), https://www.340bhealth.org/files/340B_Report_03132018_FY2015_final.pdf; AHA, *supra* note 9, at 2; Dobson et al., *supra* note 9, at 13–17.

[13] The text of the statute can be found at https://casetext.com/statute/minnesota-statutes/insurance/chapter-62j-health-care-cost-containment/prescription-drug-affordability-act/section-62j96-effective-812024-access-to-340b-drugs.

[14] Under 21 U.S.C. § 355-1 the U.S. Food and Drug Administration may require a drug to have in place a Risk Evaluation and Mitigation Strategy pursuant to which the distribution of a drug may be limited.

occupy any field through its 340B legislation and that a virtually identical Arkansas statute does not conflict with the 340B statute. *See PhRMA v. McClain*, 95 F.4th at 1143–45. *Second*, § 62J.96 does not constitute a taking under the Fifth Amendment because it does not implicate a protected property interest. And *third*, the provision is not unconstitutionally vague.

In the past three months, the Southern District of Mississippi and the Western District of Louisiana have rejected similar claims brought by AbbVie and other pharmaceutical manufacturer plaintiffs challenging materially identical state statutes.[15] *AbbVie Inc. v. Fitch*, No. 1:24-cv-00184-HSO-BWR, 2024 WL 3503965 (S.D. Miss. July 22, 2024), *appeal docketed*, No. 24-60375 (5th Cir. July 24, 2024); *PhRMA v. Fitch*, No. 1:24-cv-00160-HSO-BWR, 2024 WL 3277365 (S.D. Miss. July 1, 2024), *appeal docketed*, No. 24-60340 (5th Cir. July 5, 2024); *Novartis Pharm. Corp. v. Fitch*, ___ F. Supp. 3d ___, No. 1:24-cv-00164-HSO-BWR, 2024 WL 3276407 (S.D. Miss. July 1, 2024), *appeal docketed*, No. 24-60342 (5th Cir. July 9, 2024); *PhRMA v. Murrill*, No. 6:23-cv-00997-RRS-CBW, slip op. at ECF No. 83 (Sept. 30, 2024); *AstraZeneca Pharms. LP v. Murrill*, No. 6:23-cv-01042-RRS-CBW, slip op. at ECF No. 85 (Sept. 30, 2024); *AbbVie Inc. v. Murrill*, No. 6:23-cv-01307-RRS-CBW, slip op. at ECF No. 89 (Sept. 30, 2024). Both courts found that the analogous Mississippi and Louisiana laws are not preempted by 340B. *See AbbVie v. Fitch*, 2024 WL 3503965, at *7–16; *PhRMA v. Fitch*, 2024 WL 3277365, at

[15] Likewise, the District of Maryland denied preliminary injunction motions filed by AbbVie, PhRMA, Novartis, and AstraZeneca in a ruling from the bench last month. *See Novartis Pharms. Corp. v. Brown*, No. 24-cv-1557-MJM, ECF No. 57 (Sept. 5, 2024).

*7–13; *Novartis v. Fitch*, 2024 WL 3276407, at *5–10; *PhRMA v. Murrill*, slip op. at 6–17; *AstraZeneca Pharms. LP v. Murrill*, slip op. at 6–17; *AbbVie Inc. v. Murrill*, slip op. at 6–17. Relying on the Eighth Circuit's decision in *McClain*, the courts found that there was no conflict with the 340B statute, and that Congress did not create a federal field in which the state could not intrude in passing 340B legislation. *See AbbVie v. Fitch*, 2024 WL 3503965, at *9; *PhRMA v. Fitch*, 2024 WL 3277365, at *8; *Novartis v. Fitch*, 2024 WL 3276407, at *6; *PhRMA v. Murrill*, slip op. at 9; *AstraZeneca Pharms. LP v. Murrill*, slip op. at 9; *AbbVie Inc. v. Murrill*, slip op. at 9.

Further, the Mississippi and Louisiana courts rejected AbbVie's argument that the State statute effects an unconstitutional taking under the Fifth Amendment, citing the fundamental principle that "[g]overnmental regulation that affects a group's property interests does not constitute a taking of property where the regulated group is not required to participate in the regulated industry." *See AbbVie v. Fitch*, 2024 WL 3503965, at *17 (internal quotation marks omitted) (quoting *Burditt v. U.S. Dep't of Health & Hum. Servs.*, 934 F.2d 1362, 1376 (5th Cir. 1991)); *AbbVie v. Murrill*, slip op. at 27–31. The courts likewise rejected void-for-vagueness challenges to the analogous state statutes because, as the Mississippi court explained, "'persons of common intelligence' would not 'necessarily guess at'" what the term "interfere" means, as used in the statute. *PhRMA v. Fitch*, 2024 WL 3277365, at *13 (quoting *Women's Med. Ctr. of N.W. Houston v. Bell*, 248 F.3d 411, 421 (5th Cir. 2001)); *PhRMA v. Murrill*, slip op. at 20–24.

At bottom, AbbVie's complaint is a grab bag of meritless claims, including ones that have been squarely rejected in this Circuit and others that have been correctly rejected

elsewhere. But the company's persistence in trying to maximize its profits at the expense of Minnesota hospitals, health systems, pharmacies, and communities should come as no surprise. This is the same company that

> systematically transfers nearly all the profits on its patent protected medicines out of the United States. In fact, AbbVie reported a $4.6 billion loss in the United States in 2022—and a near $20 billion offshore profit. The reported U.S. loss is not an aberration—AbbVie has reported a U.S. loss every year between 2013 and 2022. These domestic losses occur even though AbbVie reports that it generates 75 percent of its revenue in the United States, and its blockbuster drug Humira sells at a substantially higher price in the United States than in Europe.[16]

AbbVie can no doubt afford to fund a "coordinated, nationwide attack . . . on state efforts to exercise their historic police powers," *see* Br. in Supp. of Def.'s Mot. Dismiss Am. Compl. (Def.'s Mem) at 2, ECF No. 29, but that doesn't make its legal claims any more valid.

ARGUMENT

To survive a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). AbbVie's complaint does not state a claim to relief that is plausible on its face.

[16] Brad W. Setser, *Cross-border Rx: Pharmaceutical Manufacturers and U.S. International Tax Policy* 8, Council on Foreign Relations (May 11, 2023), https://www.finance.senate.gov/imo/media/doc/Setser%20Senate%20Finance%20Testimony.pdf (last visited Aug. 5, 2024) (citing Eric Saganowsky, *AbbVie Offers Up 80% Humira Discount in EU Tender Market to Hold Off Biosimilars: Report*, Fierce Pharma (Oct. 31, 2018), https://www.fiercepharma.com/pharma/abbvie-offers-up-80-humira-discount-eu-tender-market-tohold-off-biosims-report))

I. ABBVIE'S PREEMPTION CLAIM IS FORECLOSED BY *PHRMA V. MCCLAIN*.

So far, every court to consider whether 340B preempts analogous state legislation (including the Eighth Circuit) has concluded that it does not. *PhRMA v. McClain*, 95 F.4th at 1144; *AbbVie v. Fitch*, 2024 WL 3503965, at *7; *PhRMA v. Fitch*, 2024 WL 3277365, at *8; *Novartis v. Fitch*, 2024 WL 3276407, at *6; *PhRMA v. Murrill*, slip op. at 6–17; *AbbVie v. Murrill*, slip op. at 6–17; *Novartis v. Murrill*, slip op. at 6–17. AbbVie's preemption claims are foreclosed by the Eighth Circuit's decision in *PhRMA v. McClain*. The Eighth Circuit rejected the pharmaceutical manufacturing association's contentions that the 340B program preempts the field, that the analogous Arkansas statute directly conflicts with the federal 340B statute, and that the State statute made it impossible to comply with 340B. *First*, explaining that "[t]he case for federal pre-emption is particularly weak where Congress has indicated its awareness of the operation of state law in a field of federal interest, and has nonetheless decided to stand by both concepts," the Eighth Circuit found that "Congressional silence on pharmacies in the context of 340B indicates that Congress did not intend to preempt the field." *PhRMA v. McClain*, 95 F.4th at 1144. *Second*, the court found that the Arkansas law "does not create an obstacle for pharmaceutical manufacturers to comply with 340B, rather it does the opposite: Act 1103 assists in fulfilling the purpose of 340B." *Id.* at 1144–45. *Third*, the Eighth Circuit found no impossibility preemption in light of the U.S. Food and Drug Administration's Risk Evaluation and Mitigation Strategy requirements because "[j]ust because a medication is

subject to multiple legal requirements does not make it impossible to comply with" the State law. *Id.* at 1145. *PhRMA v. McClain* disposes of AbbVie's preemption claims.[17]

II. SECTION 62J.96 DOES NOT VIOLATE THE TAKINGS CLAUSE.

AbbVie's claim under the Fifth Amendment's Takings Clause likewise fails because the challenged provision does not constitute a taking. Rather, the statute regulates AbbVie's sales of drugs for use by patients of Minnesota 340B covered entities. To our knowledge, no court has ever found that there is a property interest subject to Fifth Amendment protection where a healthcare provider or pharmaceutical company is voluntarily participating in the government program that it claims is taking its property. In fact, every court to consider the issue has found that there is no taking. *See, e.g.*, *Baker Cnty. Med. Servs., Inc. v. U.S. Atty. Gen.*, 763 F.3d 1274, 1276 (11th Cir. 2014), *cert. denied*, 575 U.S. 1008 (2015); *Minn. Ass'n of Health Care Facilities, Inc. v. Minn. Dep't of Pub. Welfare*, 742 F.2d 442, 446 (8th Cir. 1984), *cert. denied*, 469 U.S. 1215 (1985); *Garelick v. Sullivan*, 987 F.2d 913, 916 (2d Cir. 1993), *cert. denied*, 510 U.S. 821 (1993); *Burditt*, 934 F.2d at 1376; *Whitney v. Heckler*, 780 F.2d 963, 968–73 (11th Cir. 1986), *cert. denied*, 479 U.S. 813 (1986); *St. Francis Hosp. Ctr. v. Heckler*, 714 F.2d 872, 875 (7th Cir. 1983), *cert. denied*, 465 U.S. 1022 (1984); *Eli Lilly & Co. v. U.S. Dep't of Health & Hum. Servs.*, No. 1:21-cv-00081-SEB-MJD, 2021 WL 5039566, at *21 (S.D. Ind. Oct. 29, 2021); *Sanofi-Aventis U.S., LLC v. U.S. Dept. of Health & Hum. Servs.*, 570 F. Supp. 3d 129, 207–

[17] For the reasons set forth in the Attorney General's Motion to Dismiss, *PhRMA v. McClain* is not distinguishable from this case. *See* Def.'s Mem. at 17–18.

10 (D.N.J. 2021), *rev'd on other grounds*, 58 F.4th 696 (3d Cir. 2023); *AbbVie v. Fitch*, 2024 WL 3503965, at *16–20; *AbbVie v. Murrill*, slip op. at 27–31.

Indeed, all three courts to consider this issue in the 340B context have rejected the Fifth Amendment challenges of pharmaceutical companies. *Eli Lilly*, 2021 WL 5039566, at *21; *Sanofi-Aventis*, 570 F. Supp. 3d at 207–10; *AbbVie v. Fitch*, 2024 WL 3503965, at *16–20; *AbbVie v. Murrill*, slip op. at 27–31. In *Eli Lilly*, the court found that the plaintiff's voluntary participation in the 340B Drug Program "forecloses the possibility that the statute could result in an imposed taking of private property which would give rise to the constitutional right of just compensation." 2021 WL 5039566, at *21 (quoting *S.E. Ark. Hospice, Inc. v. Burwell*, 815 F.3d 448, 450 (8th Cir. 2016)). Although withdrawing from the 340B program—and therefore, necessarily, Medicaid and Medicare Part B (because 340B participation is required to participate in these markets)—would "result in a significant financial impact for" Eli Lilly, this consequence was insufficient to find legal compulsion for the purposes of the court's takings analysis. *Id.* Of course, nothing in the Minnesota law prohibits AbbVie from selling drugs to Minnesota hospitals. It simply says that if AbbVie chooses to participate in the federal 340B program, in addition to offering 340B prices to covered entities with in-house pharmacies, AbbVie must offer 340B prices to covered entities where the covered entities' patients purchase drugs at community pharmacies with which the entities have contracts.

The Southern District of Mississippi's analysis in *AbbVie v. Fitch* is instructive. There, the court rejected AbbVie's nearly identical allegations, finding that the similar Mississippi statute did not amount to an unconstitutional taking. *See AbbVie v. Fitch*, 2024

WL 3503965, at *16–20. The court concluded that because the Mississippi statute "does not compel Plaintiffs to directly sell 340B drugs to pharmacies, it does not cause takings for private use." *Id.* at *19. Further, the court declined to find that the State law effected a *per se* taking because "Plaintiffs are still only required to sell at 340B discounts to covered entities, and [covered entities] can still only have drugs dispensed to their patients." *Id.*

As an alternative basis for its holding, the court also applied the test for regulatory takings articulated by *Penn Central Transportation Co. v. City of New York*, 438 U.S. 104 (1978), which "requires 'balancing factors such as the economic impact of the regulation, its interference with reasonable investment-backed expectations, and the character of the government action.'" *AbbVie v. Fitch*, 2024 WL 3503965, at *17 (quoting *Cedar Point Nursery v. Hassid*, 594 U.S. 139, 148 (2021)). With respect to AbbVie's "reasonable investment-backed expectations," the court found that the Mississippi law "should have been foreseeable to Plaintiffs, as Section 340B has had a well-known 'gap' about how delivery must occur since Congress enacted it." *Id.* at *19 (quoting Contract Pharmacy Services, 61 Fed. Reg. 43,549, 43,550 (Aug. 23, 1996)). The district court concluded that enhanced regulation in the pharmaceutical industry—which "long has been the focus of great public concern and significant government regulation"—was foreseeable. *Id.* at *20 (quoting *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1008–09 (1984)). Further, the statute is "rationally related to a legitimate Government interest," given that "[t]he Mississippi Legislature has evidently determined that dispensation of 340B drugs at contract pharmacies advances public health, which falls squarely within its police powers." *Id.* (internal citation omitted). Lastly, "'the economic impact of the regulation' is not drastic,

and will not deprive Plaintiffs of all economically beneficial use of their products." *Id.* (internal citations omitted). The same considerations apply here.

III. THE CHALLENGED PROVISION IS NOT UNCONSTITUTIONALLY VAGUE.

AbbVie also cannot prevail in its facial challenge under the Fifth Amendment's Due Process Clause. The Supreme Court has instructed that courts "should uphold the [facial] challenge only if the enactment is impermissibly vague in all of its applications." *Vill. of Hoffman Estates v. Flipside, Hoffman Estates, Inc.*, 455 U.S. 489, 495 (1982). Further, unlike criminal statutes, which "are to be examined under a stricter vagueness test," economic regulations are "subject to a more tolerant examination." *Fogie v. THORN Americas, Inc.*, 95 F.3d 645, 650 (8th Cir. 1996) (citing *Flipside*, 455 U.S. at 498–99). Accordingly, a court will only invalidate a regulation on vagueness grounds "if it 'forbids or requires the doing of an act in terms so vague that [persons] of common intelligence must necessarily guess at its meaning and differ as to its application.'" *Stephenson v. Davenport Cmty. Sch. Dist.*, 110 F.3d 1303, 1308 (8th Cir. 1997) (quoting *Connally v. Gen. Constr. Co.*, 269 U.S. 385, 391 (1926)). That is not the case here.

That Section 62J.96 does not include a definition of "interference" does not render the statute unconstitutionally vague.[18] "Interfere" as used in the challenged provision is not

[18] Black's Law Dictionary defines "interference" as "[t]he act [of] meddling in the affairs of others" or "[a]n obstruction or hindrance." *Interference*, Black's Law Dictionary (11th ed. 2014). Merriam-Webster defines "interfere" as "to enter into or take a part in the concerns of others," "to interpose in a way that hinders or impedes," or "to act reciprocally so as to augment, diminish, or otherwise affect one another." *Interfere*, Merriam-Webster Dictionary, https://www.merriam-webster.com/dictionary/interfering (last visited Aug. 5, 2024).

unconstitutionally vague because drug "manufacturers"—the only entities subject to the provision's prohibitions—can readily assess what conduct is prohibited by its terms. Indeed, countless criminal and civil statutes prohibit "interference" without expressly defining the term. The Supreme Court of Minnesota, for example, has upheld the application of a state law that used the term "interfere" without providing a statutory definition because "[p]ersons of common intelligence need not guess at whether their conduct violates the statute," which "makes it a misdemeanor to intentionally interfere with a peace officer while the officer is engaged in the performance of his official duties." *Minnesota v. Krawsky*, 426 N.W.2d 875, 876, 878 (Minn. 1988). And there are numerous examples of the use of this term in the U.S. Code. *See, e.g.*, 15 U.S.C. § 77kk(c) ("[I]t shall be unlawful for [specified entity] . . . to do any act directly or indirectly which would interfere with or obstruct or hinder or which might be calculated to obstruct, hinder, or interfere with the policy or policies of the said Department of State or the Government of the United States . . ."); 18 U.S.C. § 245(b) ("Whoever . . . by force or threat of force willfully injures, intimidates or interferes with, or attempts to injure, intimidate or interfere with [specified persons] shall be fined . . . or imprisoned . . ."); 29 U.S.C. § 158(a) ("It shall be an unfair labor practice for an employer [] to interfere with, restrain, or coerce employees in the exercise of the rights . . . [or] to dominate or interfere with the formation or administration of any labor organization . . ."); 29 U.S.C. § 2615(a)(1) ("It shall be unlawful for any employer to interfere with, restrain, or deny the exercise of or the attempt to exercise, any right . . ."); 42 U.S.C. § 3617 ("It shall be unlawful to coerce, intimidate, threaten, or interfere with any person in the exercise or enjoyment of . . ."); 47 U.S.C. § 333

("No person shall willfully or maliciously interfere with or cause interference to any radio communications . . ."). Thus, finding the term "interfere" to render § 62J.96 unconstitutionally vague would have vast repercussions throughout the various civil and criminal codes of Minnesota and the nation.

In any event, it is disingenuous for AbbVie to assert that it does not understand what is meant by "interference." Minnesota and the seven other states that have passed these laws are specifically responding to the drug companies' efforts, since 2020, to restrict the use of contract pharmacies. The drug companies know exactly what the law is aimed at preventing. Courts must "interpret the relevant words not in a vacuum, but with reference to the statutory context, 'structure, history, and purpose.'" *Abramski v. United States*, 573 U.S. 169, 179 (2014) (citation omitted).

CONCLUSION

For the foregoing reasons, *Amici* respectfully request that the Court grant Defendant's motion to dismiss Plaintiffs' amended complaint.

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Respectfully submitted,

/s/ David W. Asp

David W. Asp (Bar No. 344850)
Derek C. Waller (Bar No. 041120)
LOCKRIDGE GRINDAL NAUEN PLLP
100 Washington Avenue S, Suite 2200
Minneapolis, MN 55401
Tel: (612) 339-6900
Fax: (612) 339-0981
dwasp@locklaw.com
dcwaller@locklaw.com

Counsel of Record

William B. Schultz*
Margaret M. Dotzel*
Alyssa Howard Card*
ZUCKERMAN SPAEDER LLP
1800 M Street NW, Suite 1000
Washington, DC 20036
Tel: (202) 778-1800
Fax: (202) 822-8106
wschultz@zuckerman.com
mdotzel@zuckerman.com
acard@zuckerman.com

**pro hac vice* motion forthcoming

Counsel for Amici Curiae