EXHIBIT
A

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF KANSAS

ABBVIE INC., *et al.*, *Plaintiffs*, *v.* KRIS KOBACH, in his official capacity as ATTORNEY GENERAL OF THE STATE OF KANSAS, *Defendant*.	Case No. 6:24-cv-01111-KHV-GEB
ASTRAZENECA PHARMACEUTICALS LP, *Plaintiff*, *v.* KRIS KOBACH, in his official capacity as ATTORNEY GENERAL OF THE STATE OF KANSAS, *Defendant*.	Case No. 6:24-cv-01112-KHV-GEB
PHARMACEUTICAL RESEARCH & MANUFACTURERS OF AMERICA, *Plaintiff*, *v.* KRIS KOBACH, in his official capacity as ATTORNEY GENERAL OF THE STATE OF KANSAS, *Defendant*.	Case No. 6:24-cv-01132-KHV-GEB
NOVARTIS PHARMACEUTICALS CORPORATION, *Plaintiff*, *v.* KRIS KOBACH, in his official capacity as ATTORNEY GENERAL OF THE STATE OF KANSAS, *Defendant*.	Case No. 5:24-cv-04068-KHV-GEB

BRIEF OF *AMICI CURIAE* AMERICAN HOSPITAL ASSOCIATION, 340B HEALTH, KANSAS HOSPITAL ASSOCIATION, COMMUNITY CARE NETWORK OF KANSAS, AND AMERICAN SOCIETY OF HEALTH-SYSTEM PHARMACISTS IN SUPPORT OF DEFENDANT'S MOTION FOR JUDGMENT ON THE PLEADINGS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT

Susan L. Mauch (Bar No. 15295)
GOODELL STRATTON EDMONDS & PALMER LLP
515 S. Kansas Ave.
Topeka, KS 66603
Tel: (785) 233-0593
Fax: (785) 233-8870
slmauch@gseplaw.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

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

STATUTES

OTHER AUTHORITIES

RULES

REGULATIONS

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 Kansas 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 **Kansas Hospital Association** (KHA) has worked for the betterment of Kansas hospitals and health systems for over 114 years. KHA provides leadership and services to its 121 acute care community member-hospitals, including more than 80 hospitals that participate in the 340B program. KHA's vision is optimal health for Kansans.

The **Community Care Network of Kansas** (CCNK) is the federally designated state primary care association representing the 19 federally qualified health centers and two federally qualified health center look-alikes in Kansas. The collective mission of these health centers is to make primary care available—including medical, dental, and behavioral health services—to all patients, regardless of ability to pay. Twenty of the 21 Kansas health centers participate in the 340B program. CCNK supports health centers as they provide high-quality, whole person care.

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, Plaintiffs AbbVie Inc. (AbbVie), Novartis Pharmaceuticals Corporation (Novartis), AstraZeneca Pharmaceuticals LP

[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.

(AstraZeneca), and 36 other major drug companies, including members of Plaintiff Pharmaceutical Research and Manufacturers of America (PhRMA) 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 89 Kansas hospitals participating in the 340B drug program, 82 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 devastating for hospitals in Kansas that provide 61% of all hospital care that is provided to Medicaid patients.[4]

Children's Mercy of Kansas City leverages 340B savings to reach more eligible patients and provide more comprehensive services. It serves as a vital safety net for uninsured, underinsured, and publicly insured children. Nearly 50 percent of its payor mix is Medicaid, and the 340B program is a critical resource in helping offset low Medicaid reimbursement rates. The 340B program also enables Children's Mercy to provide services to uninsured and underinsured patients as well as promote access to life-saving medications through a financial assistance program for patients.

---

[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.

[4] Dobson DaVanzo Health Economics Consulting, *The Role of 340B Hospitals In Serving Medicaid and Low-Income Medicare Patients: Kansas*, https://www.340bhealth.org/files/KS-340B-Low-Income15014.pdf.

Labette Health (Labette) has used the resources provided by the 340B program to re-establish hospital services in Independence, following the closure of its hospital, as well as re-establish healthcare in Oswego and Chetopa, following the closure of the hospital and clinics in Oswego. Rural hospitals serve vulnerable populations; without access to the resources needed to sustain themselves, there will be more rural hospital closures in the future.

The 340B program was a stable source of resources for rural hospitals prior to the COVID-19 pandemic, and drug companies' draconian post-2020 contract pharmacy restrictions have proven catastrophic for patients of some hospital systems in Kansas. For example, the reduction in 340B discounts forced Community HealthCare System to close its hospital and emergency services in St. Mary's and discontinue its smoking cessation program, which provided access to low-cost medications to help patients quit smoking. This significantly impacted patients with limited transportation access to affordable diabetes and chronic obstructive pulmonary disease medications.

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-

[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).

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 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]

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.[10] This is not surprising: 340B hospitals provide a disproportionate amount of uncompensated care to the country's most vulnerable patients.[11] 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).

---

[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.

[8] 340B Health, *supra* note 5, at 7 (citing Fein, *supra* note 6).

[9] 340B Health, *supra* note 5, at 6.

[10] 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.

[11] *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 10, at 2; Dobson *et al.*, *supra* note 10, at 13–17.

In April 2024, the Kansas legislature acted to address the drug industry's unprecedented assault on its health care safety net. Codified at Senate Bill 28 (S.B. 28),[12] the relevant provision does not allow a manufacturer to

> [d]eny, restrict, prohibit or otherwise interfere with the acquisition of a 340B drug by or delivery of a 340B drug to a pharmacy that is under contract with a 340B-covered entity and authorized under such contract to receive and dispense 340B drugs on behalf of the 340B covered entity, unless such receipt and dispensing of 340B drugs by such pharmacy is prohibited by the United States department of health and human services; or interfere with a pharmacy that has a contract with a 340B covered entity.

S.B. 28 § (g)(1)(A)–(B).

Seeking to halt Kansas's lawful exercise of its police power to protect public health and safety, Plaintiffs challenge S.B. 28 by bringing a slew of unmeritorious challenges—all but one of which have been considered and rejected by other courts in related cases.[13] The Court should grant Defendant's motion on all claims. *First*, S.B. 28 does not constitute a taking under the Fifth Amendment, as claimed by AstraZeneca and AbbVie, because it does not implicate a protected property interest. *Second*, the Kansas statute is not preempted by the federal 340B statute (per all Plaintiffs' claims) nor by federal patent laws (as asserted by AstraZeneca and Novartis). *Third*, the provision is not, as AbbVie and PhRMA argue, unconstitutionally vague. *Fourth*, the Kansas proviso does not, as claimed by AstraZeneca and AbbVie, violate the State constitution's one subject rule. And *fifth*, S.B. 28 does not violate the Contracts Clause, per AstraZeneca's Complaint.

[12] The text of the statute can be found at https://www.kslegislature.gov/li/b2023_24/measures/sb28/.

[13] No court has yet ruled on a plaintiff's challenge under a state constitution's single-subject clause.

ARGUMENT

A moving party is entitled to summary judgment where the movant shows that there is no genuine dispute as to any material fact and that the movant is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a) and (c). A factual dispute is "material" only if it "might affect the outcome of the suit under the governing law." *Anderson v. Liberty Lobby, Inc.,* 477 U.S. 242, 248 (1986). Defendant's Motion for Judgment on the Pleadings or, in the Alternative, for Summary Judgment demonstrates that there is no genuine dispute of material fact and that he is entitled to judgment as a matter of law.[14] *See* Def.'s Mot. Judgment on the Pleadings (Def.'s Mem.) at 15–31, ECF No. 25 (Oct. 31, 2024).

I. S.B. 28 DOES NOT VIOLATE THE TAKINGS CLAUSE.

AstraZeneca and AbbVie's claims under the Fifth Amendment's Takings Clause fail because the challenged provision does not constitute a taking. Rather, the statute regulates drug company sales of drugs for use by patients of Kansas 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 v. U.S. Dep't of Health & Hum. Servs.*, 934 F.2d 1362, 1376 (5th Cir.

[14] *Amici* take no position with respect to whether Plaintiffs' claims should be dismissed under Rule 12(b)(1) for lack of subject matter jurisdiction. *See* Def.'s Mem. at 9–15.

1991); *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, 207–10 (D.N.J. 2021), *rev'd on other grounds*, 58 F.4th 696 (3d Cir. 2023); *AbbVie v. Fitch*, No. 1:24-cv-00184-HSO-BWR, 2024 WL 3503965, at *16–20 (S.D. Miss. July 22, 2024), *appeal docketed*, No. 24-60375 (5th Cir. July 24, 2024); *PhRMA v. Murrill*, No. 6:23-cv-01042-RRS-CBW, 2024 WL 4361597, at *13–15 (W.D. La. Sept. 30, 2024).

Indeed, all four 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; *PhRMA v. Murrill*, 2024 WL 4361597, at *13–15. 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 Kansas law prohibits drug manufacturers from selling drugs to Kansas hospitals. It simply says that if a company chooses to participate in the federal 340B program, in addition to offering 340B prices to covered entities with in-house pharmacies, it 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 Mississippi court also applied the test for regulatory takings articulated by *Penn Central Transp. 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.'" *Id.* 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)). In other words, once the pharmaceutical companies abruptly terminated their 20-year policy of permitting unlimited contract pharmacies, it was foreseeable that the States would step in to protect their vulnerable hospitals. 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 court concluded that 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.

II. BOTH PREEMPTION CLAIMS FAIL ON THE MERITS.

A. Plaintiffs' 340B Preemption Claim Has Been Correctly Rejected By Every Court to Consider It.

Likewise, 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*, No. 1:24-cv-00160-HSO-BWR, 2024 WL 3277365, at *8 (S.D. Miss. July 1, 2024), *appeal docketed*, No. 24-60340 (5th Cir. July 5, 2024); *Novartis v. Fitch*, ___ F. Supp. 3d ___, No. 1:24-cv-00164-HSO-BWR, 2024 WL 3276407, at *6 (S.D. Miss. July 1, 2024), *appeal docketed*, No. 24-60342 (5th Cir. July 9, 2024); *PhRMA v. Murrill*, 2024 WL 4361597, at *9.[15]

The Eighth Circuit's decision in *PhRMA v. McClain* is instructive. The Eighth Circuit rejected PhRMA'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

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

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 analogous Arkansas law "does not create an obstacle for pharmaceutical manufacturers to comply with 340B, rather it does the opposite: [it] assists in fulfilling the purpose of 340B." *Id.* at 1144–45. *Third*, the Eighth Circuit found no impossibility preemption, explaining that "[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 Plaintiffs' 340B preemption claims.

B. The Kansas Statute is Also Not Preempted By Federal Patent Law.

AstraZeneca and Novartis also rely on a misreading of a Federal Circuit case to argue that S.B. 28 is preempted by federal patent laws. AstraZeneca Compl. ¶¶ 8, 79–83, 114–17; Novartis Compl. ¶¶ 9, 66–73, 88–90 (citing *Biotech. Indus. Org. v. District of Columbia*, 496 F.3d 1362 (Fed. Cir. 2007)). But this argument was just rejected by federal district courts in Louisiana and Mississippi. *PhRMA v. Murrill*, 2024 WL 4361597, at *9; *Novartis v. Fitch*, 2024 WL 3276407, at *10. Contrary to Novartis and AstraZeneca's allegations, *BIO* does not compel the conclusion that S.B. 28 is preempted because States are not permitted to set the price of patented drugs or to "re-balance the statutory framework of rewards and incentives insofar as it relates to inventive new drugs." Novartis ¶ 69 (quoting *BIO*, 496 F.3d at 1374). To the contrary, the Federal Circuit's holding turned on the fact that "[t]he Act's operation stands largely—indeed, exclusively—within the scope of the patent laws, and its effect is to shift the benefits of a patented invention from inventors to consumers." *BIO*, 496 F.3d at 1373–74. Unlike the law at issue in that case, S.B. 28 is *not* "targeted at the patent right," and it does not "appl[y] only to patented drugs." *Id.* at 1374. That distinction alone defeats AstraZeneca and Novartis's argument.

In addition, *BIO* did not hold that States are barred from enacting laws that touch upon patented drugs. For example, States have always retained the power to tax patented products, regulate commercial contracts involving patents, and regulate deceptive practices involving patents. *See, e.g.*, *Webber v. Virginia*, 103 U.S. 344, 347–48 (1880) ("Congress never intended that the patent laws should displace the police powers of the States . . . by which the health, good order, peace, and general welfare of the community are promoted."). Instead, *BIO* held that the District of Columbia's penalties for excessive prices on patented drugs stood as an obstacle to Congress's determination of the "proper balance between innovators' profit and consumer access to medication." 496 F.3d at 1374. Here, Congress *already* concluded that 340B pricing appropriately balances "rewards and incentives" for drug companies. *See BIO*, 496 F.3d at 1374.

On its face and in its practical effect, and in contrast to the statute at issue in *BIO*, S.B. 28 "does not set or enforce discount pricing." *PhRMA v. McClain*, 95 F.4th at 1145. Quite the contrary, the law addresses the "acquisition" by and "delivery" of prescription drugs to contract pharmacies. All it requires is for drug companies to deliver 340B drugs at congressionally determined 340B prices to contract pharmacies if a 340B provider chooses to permit its patients to receive 340B drugs at contract pharmacies rather than at its own pharmacy (assuming it has one). Kansas "is simply deterring pharmaceutical manufacturers from interfering with a covered entity's contract pharmacy arrangements." *Id*. Far from regulating pricing, S.B. 28 "incorporates by reference" the independent federal scheme, which Kansas is free to do. *See Hillsborough Cnty. v. Auto. Med. Labs.*, 471 U.S. 707, 710 (1985).

Even if AstraZeneca and Novartis's characterization of S.B. 28 as a pricing statute were correct, it still would not be preempted, as confirmed by rulings from two other courts where they made the same claims. *Novartis v. Fitch*, 2024 WL 3276407, at *10; *PhRMA v. Murrill*, 2024 WL

4361597, at *9. There is nothing in the 340B statute to indicate that Congress meant for it to be a regulatory ceiling. *See Fla. Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 147–48 (1963). In 340B, Congress expressed *no view whatsoever* on whether States can supplement federal pricing standards through requirements that may indirectly impact drug pricing. *See Hillsborough*, 471 U.S. at 717 ("[M]erely because the federal provisions were sufficiently comprehensive to meet the need identified by Congress did not mean that States and localities were barred from identifying additional needs or imposing further requirements.").

III. THE CHALLENGED PROVISION IS NOT UNCONSTITUTIONALLY VAGUE.

AbbVie and PhRMA also cannot prevail in their facial challenges under the Fifth Amendment's Due Process Clause—which were just rejected by a Louisiana district court in challenges to a materially identical statute in that State—or under the Kansas Constitution's analogous due process provisions.[16] *PhRMA v. Murrill*, 2024 WL 4361597, at *9–12. 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.*

[16] Because the Kansas Constitution's due process provisions "are given much the same effect as the clauses of the Fourteenth Amendment relating to due process and equal protection of the law," *Farley v. Engelken*, 740 P.2d 1058, 1061 (Kan. 1987), this analysis applies with equal force to AbbVie and PhRMA's state law claims. *See also Rivera v. Schwab*, 512 P.3d 168, 179–80 (Kan. 2022), *cert. denied*, 143 S. Ct. 1055 (2023).

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 S.B. 28 does not include a definition of "interference" does not render the statute unconstitutionally vague.[17] "Interfere" as used in the challenged provision is not 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, and to our knowledge, the Kansas Supreme Court has never invalidated such State statutes for vagueness. *See State v. Doyle*, 2019 WL 3047432, at *4–7 (Kan. Ct. App. July 12, 2019) (finding that a criminal statute prohibiting interference with the orderly administration of justice was not unconstitutionally vague).

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

[17] 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.

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 S.B. 28 unconstitutionally vague would have vast repercussions throughout the various civil and criminal codes of Kansas and the nation.

Kansas 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).

IV. S.B. 28 DOES NOT VIOLATE THE KANSAS CONSTITUTION’S SINGLE-SUBJECT RULE.

AbbVie and AstraZeneca are also incorrect in arguing that the challenged provision violates the Kansas Constitution’s one-subject rule. Kan. Const. art. II, § 16; AbbVie Compl. ¶¶ 17–18, 138–46; AstraZeneca Compl. ¶¶ 11, 99–107. Kansas courts evaluate laws challenged under the one-subject rule with significant latitude, only finding that such statutes run afoul of the clause where “invalidity is manifest.” *Kan. Pub. Emp. Ret. Sys. v. Reimer & Koger Assocs., Inc.*, 941 P.2d 1321, 1347 (Kan. 1997). As long as “the provisions of the bill are ‘all germane to the subject expressed in the title,’” a Kansas law “will be invalidated only where ‘an act embraces two or more dissimilar and discordant subjects that cannot reasonably be considered as having any legitimate connection with or relationship to each other.” *Id.* (citation omitted).

As Defendant explains in his Motion, "[t]he challenged portion of the bill appropriates funds to the Attorney General and, *inter alia,* directs enforcement of the KCPA," and accordingly, "S.B. 28 has but a single subject—appropriations." Def.'s Mem. at 29. Under the deferential test set forth by the Kansas Supreme Court, S.B. 28 does not violate the one-subject rule.

V. THE KANSAS STATUTE DOES NOT VIOLATE THE CONTRACTS CLAUSE.

The Western District of Louisiana has also rejected AstraZeneca's Contracts Clause claim against the analogous statute in that State. *PhRMA v. Murrill*, 2024 WL 4361597, at *12–13. The Contract Clause prohibits States from passing any law that "impair[s] the Obligations of Contracts[.]" U.S. Const. Art. I, § 10. The Supreme Court's two-step analysis for Contracts Clause challenges requires first that a court determine whether the State law at issue substantially impairs a contractual relationship, and if so, whether it did so for a legitimate purpose. *Sveen v. Melin*, 584 U.S. 811, 819 (2018).

As in the Louisiana case, AstraZeneca's Contracts Clause challenge fails at the first step. The contract on which AstraZeneca relies, the pharmaceutical pricing agreement (PPA), is unaffected by the Kansas statute. Under the 340B program, a drug manufacturer that participates in Medicaid and Medicare Part B is required to enter a PPA with the Secretary of HHS pursuant to which it must offer 340B covered entities outpatient drugs at or below a statutorily-determined discount price, referred to as the ceiling price. 42 U.S.C. § 256b(a)(1). The terms of the PPA basically parrot the federal 340B statute. As the Supreme Court has explained, "the PPAs simply incorporate statutory obligations and record the manufacturers' agreement to abide by them. The form agreements, composed by HHS, contain no negotiable terms . . . . [T]he 340B Program agreements serve as the means by which drug manufacturers opt into the statutory scheme." *Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 118 (2011).

AstraZeneca is incorrect that "S.B. 28 seeks to unilaterally expand AstraZeneca's obligations under" its PPA. AstraZeneca Compl. ¶ 86. The Kansas law does not change or expand the definition of covered entities that are entitled to 340B discounts. Nor does S.B. 28 change what prices drug companies may charge covered entities. Rather, it only affects the *delivery* of 340B drugs, which is not addressed in the PPA. AstraZeneca cannot identify any way in which the provision expands or contradicts its PPA because, by simply incorporating the 340B statute, the PPA is silent as to delivery.

The case on which AstraZeneca relies is inapposite. In *Allied Structural Steel Co. v. Spannaus*, the Supreme Court struck down a Minnesota law that required a company to provide additional pension benefits after it had agreed to provide such benefits under specific contractual provision. 438 U.S. 234, 245–46 (1978). Unlike the Kansas statute here, where the terms of the PPA remain unchanged, the law in that case effectively changed the terms of the contract.

Moreover, even if S.B. 28 did substantially impair the contractual relationship between AstraZeneca and HHS (it does not), the Kansas legislature would have had a legitimate purpose for doing so. The Supreme Court has "repeatedly held that unless the State is itself a contracting party, courts should 'properly defer to legislative judgment as to the necessity and reasonableness of a particular measure.'" *Keystone Bituminous Coal Ass'n v. DeBenedictis*, 480 U.S. 470, 505 (1987) (quoting *Energy Reserves Group, Inc. v. Kan. Power & Light Co.*, 459 U.S. 400, 413 (1983) (internal citations omitted)). Over four years ago, AstraZeneca suddenly refused to provide 340B discounts to covered entities that relied on contract pharmacies to dispense their drugs to 340B patients, even though up until then, it had been doing just that. Now, AstraZeneca permits a 340B covered entity to rely on a single contract pharmacy if it has no in-house pharmacy. For the reasons explained above, *supra* at 2–7, savings from 340B discounts allow covered entities to provide life-

saving health care and programs in Kansas. S.B. 28 merely requires that drug companies continue to do what they were doing prior to 2020—that is, provide the 340B discount to drugs purchased by patients of statutorily-defined covered entities, even when the covered entities rely on contract pharmacies to dispense those drugs.

Faced with the drug industry's synchronized strike on Kansas' health care safety net, the Kansas legislature had a significant and legitimate justification for passing S.B. 28. Any impact the legislation has on drug companies is reasonable and necessary. It is reasonable because the impact on the drug industry of requiring such discounts is minimal when compared to its profits,[18] while the impact of not permitting the discounts is devastating to covered entities that often operate on negative margins.[19]

CONCLUSION

For the foregoing reasons, *Amici* respectfully request that the Court grant Defendant's motion for judgment on the pleadings or, in the alternative, for summary judgment.

[18] *See* Fred D. Ledley et al., *Profitability of Large Pharmaceutical Companies Compared With Other Large Public Companies*, 323(9) JAMA 834–43 (Mar. 3, 2020), https://jamanetwork.com/journals/jama/fullarticle/2762308 (finding that between 2010 and 2018, "the median net income (earnings) expressed as a fraction of revenue was significantly greater for pharmaceutical companies compared with nonpharmaceutical companies (13.8% vs 7.7%)").

[19] *See, e.g.*, Dobson et al., *The Role of 340B Hospitals in Serving Medicaid and Low-income Medicare Patients*, 3-4.

Dated: November 7, 2024

Respectfully submitted,

/s/ Susan L. Mauch

Susan L. Mauch (Bar No. 15295)
GOODELL STRATTON EDMONDS & PALMER LLP
515 S. Kansas Ave.
Topeka, KS 66603
Tel: (785) 233-0593
Fax: (785) 233-8870
slmauch@gseplaw.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