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[WBA, CVS, WMT] 340B Case on Deck at SCOTUS Conference; Regardless of Resolution, Target Remains on 340B

We could see some short-term positive news for **retail, mail-order and specialty pharmacies (WBA, CVS, WMT, UNH, CI)** if the Supreme Court decides not to hear the appeal of *PhRMA v. McClain*, a development that should be made public next week. In the event they do take up the case, we lean towards the Court affirming the lower court ruling but benefits for contract pharmacies would take longer to play since a ruling would not occur until the spring. The Court will meet this Friday at a closed-door conference to determine which cases it will review and will publicly announce which cases they have granted cert sometime next week.

While affirming *PhRMA v. McClain* would be positive for the pharmacy sector, such a decision would not diminish the ongoing scrutiny and put to rest the extant legal attacks on the federal 340B drug-discount program.

In fact, the program's sprawling growth, ongoing spate of separate federal lawsuits, and the political desire to confront a perceived culprit of higher healthcare costs is likely to force the issue onto the next Congress' agenda. Plus, interest for reforms from various House GOP members, incoming Senate HELP Chairman Bill Cassidy (R-LA), and incoming Senate Majority Leader John Thune (R-SD), who is also a longtime rural hospital supporter and a member of the bipartisan 340B workgroup, puts the issue onto the agenda. Yet, changes to 340B are not a first-order event and are likely to be dealt with *after* government funding and tax reconciliation package; we are skeptical that 340B reforms would be allowed under reconciliation.

Ultimately, we envision a legislative compromise that:

- Preserves the use of these **contract pharmacies**.
- Crimps the growth of additional sites of participating **non-profit and government-backed hospitals** (with perhaps favorable treatment for rural facilities) and assess additional costs on them via enhanced disclosures requirements and federal audits, which could advantage neighboring **for-profit hospitals**.
- Reaffirm participating **drug makers (JNJ, LLY, BMY, SNY, NVO, UTHR, VRTX)** must provide the discounted drug without conditions to the 340B entities and their contract pharmacies, though blessing the use of rebate or cash-replenishment models, instead of an upfront discount.

PhRMA v. McClain questions whether an Arkansas state law that bars biopharma manufacturers from imposing conditions on 340B hospitals/clinics' contract pharmacies is preempted by federal law or is simply unconstitutional. The federal district court and 8th Circuit Court of Appeals unanimously sided with Arkansas, which indirectly preserved the ability for 340B entities to contract with pharmacies in dispensing discounted drugs.

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Walgreens Boots Alliance Inc (WBA)

Price:	\$9.00
52-Week High:	\$27.05
52-Week Low:	\$8.08

CVS Health Corp (CVS)

Price:	\$59.54
52-Week High:	\$83.25
52-Week Low:	\$52.71

Walmart Inc (WMT)

Price:	\$93.52
52-Week High:	\$92.99
52-Week Low:	\$49.85

UnitedHealth Group Incorporated (UNH)

Price:	\$606.94
52-Week High:	\$630.73
52-Week Low:	\$436.38

Cigna Corp (CI)

Price:	\$338.59
52-Week High:	\$370.82
52-Week Low:	\$253.95

Johnson & Johnson (JNJ)

Price:	\$153.00
52-Week High:	\$168.85
52-Week Low:	\$143.13

Eli Lilly and Company (LLY)

Price:	\$814.81
52-Week High:	\$972.53
52-Week Low:	\$561.65

Nearly two handfuls of states have enacted similar laws as Arkansas, which claims that Congress did not intend to prevent state regulation of pharmacies and that if Congress wanted federal 340B law to override state law, it would have stated such. While a few of the other state laws are being challenged by the drug industry, none have advanced far enough that there is a conflicting appellate opinion.

Add in the Court's bias in favor of state rights, states as traditional regulators of pharmacy, discomfort with broad federal preemption, and reliance on specific statutory language, and we think the Court will either reject the application for SCOTUS review or if they take up the case (only 4 justices are needed to grant cert), a majority will likely ultimately side with Arkansas, benefiting contract pharmacies. Should the Court decide to grant cert, we suspect oral arguments would occur in early spring and a ruling handed down in the late spring.

Recall the 340B drug discount program is a decades-old federal drug discount program established to facilitate statutory formula-set discounts for outpatient drugs for eligible non-profit hospitals and clinics that disproportionately cater to poor and uninsured individuals. Under the program, it is claimed that 340B providers average savings of 25%-50% on their pharmaceutical purchases. Drug makers volunteer to participate and extend the discounted price so they can participate in Medicaid. The original intention was that eligible providers would use the savings from these discounts to provide additional services to the poor and uninsured.

Since its inception, the 340B program has grown significantly, both in the number of participating providers (in 2023, ~55,000), drug volumes purchased through the program (in 2023, \$66.3B), and use of contract pharmacies (in 2023, ~33,000 by location and ~194,000 by contract pharmacy arrangement since most retail, specialty and mail-order pharmacies have multiple contracts with a provider).

Besides accusation about the program's bloated nature, the key complaints lodged against the program are that: 1) low-income and uninsured individuals are not getting the benefits from the discounts; and 2) it is not clear how the savings are being used by the hospital.

The biopharma industry alleges that hospitals are gaming the system by diverting the discounted medicines to insured patients who pay higher reimbursements or through billing for duplicate discounts with Medicaid. Meanwhile, hospitals and their contract pharmacies argue the drug makers refuse to pay the discount and lob unreasonable conditions and arbitrary audits.

These accusations have boiled over into multiple lawsuits at various stages, many of them falling into two distinct categories. The first involves the legality of drug makers participating in the 340B program placing conditions on contract pharmacies of 340B hospitals and clinics. While a number are still at the federal lawsuits, some had already advanced to the appellate stage, with two federal appeals courts siding with biopharma and permitting their restrictions on contract pharmacies, since the underlying statute does not specify contract pharmacies even if longstanding guidance does, while there remains one federal appellate decision outstanding.

The other type involves individual drug companies (**JNJ, LLY, BMY, SNY**) changing their participation in the program. Instead of offering an upfront discount for the drugs acquired by 340B entities, they are providing either a rebate or a cash-replenishment model to 340B hospitals and clinics after buying the drug at full-freight to achieve the same "discount". The federal government has rejected this design, and the manufacturers have sued with the claims that the law specifically contemplates the use of rebates or discounts and that their new model is not in violation of statute.

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