No. 22-1676

In the United States Court of Appeals
for the Third Circuit

ASTRAZENECA PHARMACEUTICALS LP,
Appellee

v.

SECRETARY UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; GENERAL COUNSEL UNITED STATES DEPARTMENT OF HEALTH HUMAN SERVICES; ADMINISTRATOR HEALTH RESOURCES AND SERVICES ADMINISTRATION; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; HEALTH RESOURCES AND SERVICES ADMINISTRATION,
Appellants

On Appeal from the United States District Court for the District of Delaware, Case No. 1-21-cv-00027

BRIEF OF COMMUNITY ONCOLOGY ALLIANCE, INC. AS *AMICUS CURIAE* IN SUPPORT OF PLAINTIFF-APPELLEE ASTRAZENECA PHARMACEUTICALS LP AND AFFIRMANCE

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United States Court of Appeals for the Third Circuit

Corporate Disclosure Statement and Statement of Financial Interest

No. 22-1676

ASTRAZENECA PHARMACEUTICALS LP

v.

SECRETARY, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, ET AL.

Instructions

Pursuant to Rule 26.1, Federal Rules of Appellate Procedure any nongovernmental corporate party to a proceeding before this Court must file a statement identifying all of its parent corporations and listing any publicly held company that owns 10% or more of the party's stock.

Third Circuit LAR 26.1(b) requires that every party to an appeal must identify on the Corporate Disclosure Statement required by Rule 26.1, Federal Rules of Appellate Procedure, every publicly owned corporation not a party to the appeal, if any, that has a financial interest in the outcome of the litigation and the nature of that interest. This information need be provided only if a party has something to report under that section of the LAR.

In all bankruptcy appeals counsel for the debtor or trustee of the bankruptcy estate shall provide a list identifying: 1) the debtor if not named in the caption; 2) the members of the creditors' committee or the top 20 unsecured creditors; and, 3) any entity not named in the caption which is an active participant in the bankruptcy proceedings. If the debtor or the bankruptcy estate is not a party to the proceedings before this Court, the appellant must file this list. LAR 26.1(c).

The purpose of collecting the information in the Corporate Disclosure and Financial Interest Statements is to provide the judges with information about any conflicts of interest which would prevent them from hearing the case.

The completed Corporate Disclosure Statement and Statement of Financial Interest Form must, if required, must be filed upon the filing of a motion, response, petition or answer in this Court, or upon the filing of the party's principal brief, whichever occurs first. A copy of the statement must also be included in the party's principal brief before the table of contents regardless of whether the statement has previously been filed. Rule 26.1(b) and (c), Federal Rules of Appellate Procedure.

If additional space is needed, please attach a new page.

Pursuant to Rule 26.1 and Third Circuit LAR 26.1, COMMUNITY ONCOLOGY ALLIANCE, INC makes the following disclosure:
(Name of Party)

1) For non-governmental corporate parties please list all parent corporations: N/A

2) For non-governmental corporate parties please list all publicly held companies that hold 10% or more of the party's stock:
N/A

3) If there is a publicly held corporation which is not a party to the proceeding before this Court but which has as a financial interest in the outcome of the proceeding, please identify all such parties and specify the nature of the financial interest or interests:
N/A

4) In all bankruptcy appeals counsel for the debtor or trustee of the bankruptcy estate must list: 1) the debtor, if not identified in the case caption; 2) the members of the creditors' committee or the top 20 unsecured creditors; and, 3) any entity not named in the caption which is active participant in the bankruptcy proceeding. If the debtor or trustee is not participating in the appeal, this information must be provided by appellant.
N/A

/s/ Jonathan E. Levitt
(Signature of Counsel or Party)

Dated: 7/28/22

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Brandy Snyder et al., HOPA News, *An Overview of White Bagging: The Effect on Systems and Potential Strategies*, Hemotology/Oncology Pharmacy Association, Vol. 18, Issue 3, https://www.hoparx.org/hopa-news/volume-18-issue-3-2021/all-pages 27

STATEMENT OF IDENTITY AND INTEREST OF THE *AMICUS*[1]

Pursuant to Federal Rule of Appellate Procedure 29(a)(2) and Third Circuit Rule 29, *amicus* Community Oncology Alliance, Inc. ("COA") submits this brief in support of Plaintiffs-Appellees AstraZeneca Pharmaceuticals LP. COA is a non-profit organization dedicated to advocating for community oncology practices and, most importantly, the patients they serve. For close to twenty years, COA has built a national grassroots network of community oncology practices to enhance the effectiveness and efficiency of cancer care. COA has a compelling interest in ensuring that all patients with cancer have access to local, affordable health care.

COA absolutely supports the 340B Drug Pricing Program ("340B"), especially in ensuring that Americans in need receive financial help with their cancer drugs and other critical therapies. However, COA is extremely concerned that the out-of-control growth of 340B contract pharmacies ("CPs"), particularly mail order and specialty pharmacies owned or affiliated with pharmacy benefit managers ("PBMs"), has increasingly diverted 340B discounts into the coffers of Fortune 500 companies as opposed to helping patients in need. Congress vested non-profit safety-net providers with 340B drug discounts; they never contemplated that 340B would become a profit center for mega for-profit corporations or even large "nonprofit" health systems. As

[1] Pursuant to Fed. R. App. P. 29(a)(2), all parties have consented to the filing of this *amicus curiae* brief. Under Fed. R. App. P. 29(a)(E)(4), COA states that no party or its counsel authored this brief in whole or in part, or contributed money intended to fund the filing of this brief.

such, COA is compelled to submit this *amicus* brief to inform the Court how 340B has mutated from a well-intentioned community benefit to a virtual ATM cash machine due to the exponential growth in CPs, especially those owned by PBMs or affiliated under the same corporation.

INTRODUCTION AND SUMMARY OF ARGUMENT

Congress established 340B in 1992 with the goal of making health care affordable and accessible at specified safety-net providers serving certain uninsured, low-income, or otherwise vulnerable patients. The mutation of 340B, especially CP arrangements with 340B covered entities, is such that the largest PBMs have found an extremely profitable source of drug discounts. Instead of promoting accessible and affordable health care for the nation's most vulnerable patients, 340B has been distorted into benefitting some of America's largest public companies.

The number of vertically integrated CPs participating in 340B, and the number of arrangements these for-profit pharmacies have with 340B covered entities ("CEs"), has grown exponentially since the 2010 guidance issued by the Health Resources and Services Administration ("HRSA"), which permitted CEs to enter into virtually unlimited and unconstrained arrangements with CPs.

Over the last two decades, extreme consolidation and vertically integrated business models—combined with flawed government guidance and lax oversight—have allowed the largest insurers and PBMs, through their owned or affiliated CPs, to increasingly dominate (and reap substantial profits from) 340B. The profits PBMs

generate through 340B are retained; these savings are not passed on to patients. Making matters worse, the enormous profits these for-profit entities retain through 340B incentivizes them to monopolize the broader pharmacy market, driving independent pharmacies out of business.

Today's 340B has diverged significantly from the one Congress designed, with the growth of for-profit CPs a primary driver. The expansive use of 340B CPs has occurred without sufficient oversight or regulation and, more importantly, has actually detracted from the 340B safety-net mission. Put simply, 340B has become a profit center for large for-profit corporations, to the detriment of patients in need.

FACTUAL SUMMARY

A. 340B was Created to Benefit America's Most Vulnerable Patients and the CEs that Serve Them

Congress designed 340B to assist certain healthcare facilities serving poor, uninsured or otherwise vulnerable populations. *See* Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 602 (codified as amended at 42 U.S.C. § 256b). Under 340B, drug manufacturers—in exchange for Medicaid and Medicare Part B drug coverage—are required to charge CEs no more than a significantly discounted "ceiling price" on certain outpatient prescription drugs purchased by the CEs for their patients. 42 U.S.C. § 256b(a)(1),(4). 340B's purpose is "to enable covered entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102-384, pt. 2 at 12 (1992). It is fundamental to 340B that CEs are credited for their ability to "provide direct clinical care to large

numbers of uninsured Americans" regardless of the patient's ability to pay. *See* H.R. Rep. No. 102-384, pt. 2, at 12 (Sept. 22, 1992). Indeed, HRSA, the agency charged with administering 340B, has opined that 340B is designed so that CEs would "pass all or significant part of the discount to their patients." HRSA, *Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services*, 61 Fed. Reg. 43,551 (Aug. 23, 1996). Thus, the clear purpose of 340B is that uninsured, poor, and otherwise vulnerable patients would benefit by receiving discounted drugs or charity care.

Under 340B, CEs can acquire drugs from manufacturers at extreme discounts from what is normally available. In turn, CEs are (in theory) able to "pass on" those savings to their patients through lower costs for medications, or, as contemplated by 340B itself, CEs can seek reimbursement for 340B drugs in the normal course and use those greater profit margins to subsidize other unfunded areas of their operations. Because certain CEs, such as small community health centers, may not have in-house pharmacies, HRSA issued sub-regulatory guidance in 1996 permitting CEs to "contract" with outside pharmacies (i.e., CPs). *See* 61 F.R. at 43,549.

Initially, HRSA restricted CEs to contracting with only a single CP. *Id.* at 43,551. In 2010, however, HRSA dramatically shifted the 340B CP landscape by permitting CEs to maintain an unlimited number of CP relationships. *See* 75 F.R. 10,272-01 (Mar. 5, 2010). In the wake of this HRSA guidance, for-profit pharmacies, especially those owned or affiliated with PBMs, have seized on the opportunity to capitalize on substantial 340B drug discounts. In effect, the 2010 guidance provided an open door

for sophisticated for-profit pharmacies (and their parent and affiliated companies) to realize substantial drug discounts through a federal drug pricing program designed to aid non-profit CEs caring for vulnerable patients.

B. The 340B Pharmacy Benefits Landscape

Any examination of 340B's use of CPs must be grounded in a sound understanding of the relationships between the relevant stakeholders. On the front line of care serving 340B patients are providers: CEs and CPs. CEs include a select number of hospitals, clinics, and health centers that serve a disproportionate share of poor patients in urban and rural areas. 340B specifically limits the entities eligible to participate as CEs. *See* 42 U.S.C. § 256b(a)(4). Conversely, 340B provides little guidance on the use and eligibility of CPs. 340B CPs include retail, specialty, and mail-order pharmacies.

There are differences between retail, mail order, specialty and community oncology pharmacies. Patients typically use a physical retail pharmacy for short-term illness and more stable long-term conditions, such as hypertension. Mail order pharmacies typically mail longer day supplies of medications, such as a 90-day supply, directly to patients. Specialty pharmacies (both with physical retail and mail order locations) and community oncology practices dispense and administer drugs typically requiring special handling and storage requirements.

PBMs are fiscal intermediaries that administer and manage drug benefits on behalf of health insurance plans. But, as discussed below, the distinction between PBMs

and health plans are blurred. PBMs are primarily responsible for processing and paying prescription drug claims submitted by providers on behalf of covered beneficiaries. The largest PBMs unilaterally dictate the provider's reimbursement for dispensing or administering the drug and the health plan will, in turn, reimburse the PBM for the amount paid to the provider. PBMs also provide a host of related services associated with the administration of pharmacy benefits including formulary design and management, rebate negotiation, and maintaining a network of providers.

The largest PBMs are owned or affiliated with the nation's largest health insurance companies. These PBMs also own or are affiliated with retail, mail-order and/or specialty pharmacies. As a result, a small number of huge, vertically integrated companies wield near limitless power and influence in the prescription drug market and the adjudication of 340B eligible claims. Today, three PBMs control nearly 80 percent of the prescription drug market: CVS Caremark ("Caremark"), Express Scripts, Inc. ("ESI") and OptumRx.[2] Each of these PBMs also share common ownership with a major insurer and specialty pharmacy. Caremark is owned by CVS Health, which also owns health insurers Aetna[3] and SilverScript[4] and CVS retail, mail order and specialty

[2] Adam Fein ("Fein"), Drug Channels ("DC"), *The Top PBMs of 2021: The Big Get Event Bigger*, (Apr. 5, 2022, https://www.drugchannels.net/2022/04/the-top-pharmacy-benefit-managers-of.html

[3] CVSHealth, A New Path to Better Health, https://cvshealth.com/aetna (last visited July 13, 2022).

[4] SilverScript, About SilverScript Insurance Company, https://www.silverscript.com/about-us (last visited July 13, 2022).

pharmacies.[5] Health insurer Cigna owns ESI[6], which operates its own mail-order pharmacy,[7] and Accredo Health, Inc., which operates Accredo Specialty Pharmacy.[8] Insurance company UnitedHealth Group owns OptumRx,[9] which owns OptumRx Specialty Pharmacy.[10] Further, Walgreens Boots Alliance ("Walgreens") is vertically integrated with the PBM Prime Therapeutics, which in turn operates the specialty and mail order pharmacy AllianceRx Walgreens Prime.[11]

The process of determining whether a particular claim is 340B eligible is complex, and responsibility for compliance lies with the CE. Generally, CEs hire third-party administrators ("TPAs") to retroactively determine 340B eligibility.[12] TPAs provide claims processing and management services and retroactively determine which claims are 340B eligible. CEs rely on TPAs for 340B compliance and to maximize their

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[5] CVSHealth, Retail Pharmacy, https://www.cvshealth.com/about/our-offerings/retail-pharmacy, CVSHealth, Specialty Pharmacy, https://cvshealth.com/about/our-offerings/cvs-specialty (last visited July 13, 2022).
[6] Bruce Japsen, *Cigna-Express Scripts Merger's A Done Deal*, Forbes, Dec. 19, 2018, https://www.forbes.com/sites/brucejapsen/2018/12/19/cigna-express-scripts-merger-a-done-deal-by-thursday/#261d98a55688).
[7] Express Scripts, express-scripts.com.
[8] Express Scripts, Specialty Pharmacies: FAQs, express-scripts.com.
[9] UnitedHealth Group, Optum Products & Services, https://www.unitedhealthgroup.com/businesses/optum.html.
[10] Optum, Specialty Pharmacy, https://specialty.optumrx.com/ (last visited July 13, 2022).
[11] Walgreens, Walgreens and Prime Therapeutics Complete Formation of AllianceRx Walgreens Prime, https://news.walgreens.com/press-center/news/walgreens-and-prime-therapeutics-complete-formation-of-alliancerx-walgreens-prime-a-combined-central-specialty-pharmacy-and-mail-services-company.htm (last visited May 25, 2022).
[12] OIG Report, *Contract Pharmacy Arrangements in the 340B Program*, (Feb. 4, 2014), at 5, https://oig.hhs.gov/oei/reports/oei-05-13-00431.pdf

received benefits. The largest TPAs are also vertically integrated with the largest PBMs: CVS Health owns Wellpartner.[13] Cigna owns Verity Solutions.[14] Walgreens owns 340B Complete and Shields Health Solutions.[15]

C. The Exponential Growth of Contract Pharmacies

Approximately 14% of all pharmaceutical sales in the United States, or $93.6 billion, are accounted for under 340B.[16] 340B has grown five times faster than the overall drug market,[17] with 340B expenditures quadrupling since 2014.[18] In terms of magnitude, it is the second largest federal drug program, behind only Medicare Part D. By 2026, 340B is expected to exceed the size of both Medicaid and Medicare.[19] The primary component driving 340B's tremendous expansion is not a rise in the number of 340B eligible patients or increased need for charity care, but rather the expansive use of CPs, particularly CPs owned or affiliated with PBMs.

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[13] Aaron Vandervelde et al. ("Vandervelde"), BRG, *For-Profit Pharmacy Participation in 340B Program*, at 4 (Oct. 2020), https://bit.ly/36X0eUG; *see also* AIR340B ("AIR340B"), *The Impact and Growth in 340B Contract Pharmacy Arrangements – Six Years Later*, at 8, https://340breport.com/wp-content/uploads/2020/12/AIR340B-Report-on-the-Impact-of-Growth-in-340B-Contract-Pharmacy-Arrangements.pdf

[14] Vandervelde, at 4; *see also* AIR340B, at 8.

[15] *Id.*

[16] Rory Martin, IQVIA, *340B Program Continues to Grow While Contract Pharmacy Restrictions Take Effect*, at 2.

[17] *Id.*

[18] Fein, DC, *Exclusive: The 340B Program Soared to $38 Billion in 2020 – Up 27% vs 2019,* https://www.drugchannels.net/2021/06/exclusive-340b-program-soared-to-38.html

[19] BRG, *340B Program at a Glance*, https://media.thinkbrg.com/wp-content/uploads/2021/12/09062840/340B_Forecast-Report-Infographic_2021.pdf .

As a result of HRSA's 2010 guidance, both the number of CPs participating in 340B and the number of arrangements these CPs maintain with CEs grew exponentially. In January 2010, less than 1,300 unique locations participated as CPs.[20] Currently, there are approximately 32,000 unique CPs participating in 340B—half of the entire U.S. pharmacy industry—with more than 168,500 contractual relationships with CEs.[21] The number of CP arrangements with CEs grew by 4,228%,[22] with each hospital CE utilizing 22 different CPs on average, and federal grantees utilizing 11 different CPs.[23] Further, the distance between hospital CEs and their CPs has increased dramatically, from an average of 34 miles in 2010 to 334 miles in 2020.[24] In some instances, the CP can be thousands of miles away from the CE.[25] Today, 28% of 340B revenue is generated by the use of CPs.[26] These 30,000+ CPs share in the 340B

[20] Fein, DC, *Exclusive: Five Pharmacy Chains and PBMs Dominate 2022's Still-Booming 340B Pharmacy Market*, https://www.drugchannels.net/2022/07/exclusive-five-pharmacies-and-pbms.html

[21] *Id.*

[22] Vandervelde, at 4; *see also* AIR340B, at 1.

[23] Vandervelde, at 7; *see also* Nephron ("Nephron"), *Decade-Long 34B Tailwind Gives Way to Significant Pharmacy Headwind in 1Q 2022*.

[24] Vandervelde, at 4.

[25] *Id.*

[26] Ed Silverman, STAT, *Two dozen states side with HHS in its raucous dispute with pharma over a drug discount program*, (May 16, 2022), https://www.statnews.com/pharmalot/2022/05/16/hhs-340b-hospitals-prescription-drugs/?utm_campaign=pharmalittle&utm_medium=email&_hsmi=21%E2%80%A6

discounts from manufacturers; however, the current regulatory landscape imposes no requirement that they use those discounts to help patients.[27]

In recent years, 340B CP growth has skyrocketed with specialty and mail order pharmacies. Since 2017, 340B purchases flowing through specialty and mail order pharmacies have grown by 56% per year; six times faster than non-340B specialty and mail order pharmacy purchases.[28] Compared to the average annual growth of non-340B mail order purchases (i.e., 9%),[29] the recent growth of 340B mail order is over six times greater. The growth in specialty and mail order has been quickest in oncology.[30] Oncology's share of 340B sales has increased from 37.5% in 2015 to 52.4% in 2019, and oncology-generated 340B profits increased from 19.1% to 32.6% of total 340B provider profits over the same period.[31] As discussed in more detail below, these dramatic increases are due in large part because of increased participation in 340B by the four largest (and vertically integrated) specialty and mail order pharmacies owned

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[27] GAO, GAO-18-840, *Drug Discounts in the 340B Program Offer Benefits, But Federal Oversight Needs Improvement*, (June 2018), at 31, https://bit.ly/3vKXcxg ("GAO 2018") (noting that 57% of surveyed hospital-CEs provided *no 340B discounts* to patients receiving their prescriptions at CPs).

[28] Fein, DC, *Specialty Pharmacy's Explosive 340B Growth*, https://www.drugchannels.net/2021/07/specialty-pharmacys-explosive-340b.html

[29] *Id.*

[30] Neal Masia, PhD, AIR340B, *340B Drug Pricing Program: Analysis Reveals $40 Billion in Profits in 2019*, at 1, https://340breform.org/wp-content/uploads/2021/05/AIR340B-Neal-Masia-Report.pdf (noting that "oncology drugs dominate [340B] , accounting for a large and growing share of total program profits").

[31] *Id.*

by or affiliated with the top PBMs: Caremark/CVS Specialty, ESI/Accredo, OptumRx/Optum Specialty Pharmacy, and AllianceRx Walgreens Prime/Walgreens.[32]

The significant growth of 340B CP arrangements, especially PBM specialty and mail order CPs, is attributable to the substantial profit potential of 340B and virtually no CP oversight by HRSA. Based on the terms of their contracts with CEs, CPs retain a substantial portion, generally 25-35%, of total 340B discounts.[33] Typically, CEs pay the CP a flat fee for each eligible prescription dispensed, which generally ranges from $6-$15, but can be upwards of $1,750 per prescription.[34] Additionally, some CEs "also agree[] to pay [contract] pharmacies a percentage of the revenue generated by each [340B] prescription," which can be as much as 20%.[35] With these favorable reimbursements, the average profit margin for CPs on 340B claims for brand name drugs is an astounding 72%, compared with just 22% for non-340B brand name drug claims.[36] Put another way, a CP's profit margin is approximately three times greater for

[32] Maia Anderson, Becker's Hospital Review, *Top 15 specialty pharmacies by revenue,* (April 28, 2020), https://www.beckershospitalreview.com/pharmacy/top-15-specialty-pharmacies-by-revenue.html; *see also* Fein, DC, *PBM-Owned Specialty Pharmacies Expand Their Role In-and Profits From-the 340B Program*, https://www.drugchannels.net/2020/07/pbm-owned-specialty-pharmacies-expand.html

[33] Fein, DC, *Exclusive: Five Pharmacy Chains and PBMs Dominate 2022's Still-Booming Contract Pharmacy Market*, https://www.drugchannels.net/2022/07/exclusive-five-pharmacies-and-pbms.html

[34] GAO 2018, at 26.

[35] *Id.*

[36] Vandervelde, at 4.

340B brand name claims than for non-340B. This profit sharing between CEs and CPs indicates that CPs owned or associated with PBMs are a primary stakeholder in 340B.

The exponential growth of CPs, on its own, would not be an issue if it resulted in increased access and affordability of care to patients of CEs. But financial help for patients is "*negatively correlated"* with growth of 340B CPs.[37] The "growth of contracts with 340B hospitals [is] uncorrelated with uninsured rates, poverty rates, or areas of medical underservice."[38] In direct contradiction to the spirit of 340B—serving poor neighborhoods and patients—following HRSA's reversal of its one-CP policy, "the percent of 340B pharmacies in the *lowest* income neighborhoods *declined by 5.6%*".[39] Conversely, "the percentage of 340B pharmacies in the *highest* income neighborhoods *increased* by 5.0%".[40] CP growth has therefore been concentrated in affluent neighborhoods, with predominately fully insured patients.[41] HRSA's 2010 Guidance has

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[37] *Id.* (emphasis added); *see also* Bruce Levinson, *Measuring the Effectiveness of the 340B Program*, at 4, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3284078

[38] Sayeh Nikpay et al., *Association of 340B Contract Pharmacy Growth With County-Level Characteristics*, American Journal of Managed Care, https://www.ajmc.com/view/association-of-340b-contract-pharmacy-growth-with-county-level-characteristics

[39] Dr. John K. Lin, et al., *Assessment of US Pharmacies Contracted With Health Care Institutions Under the 340B Drug Pricing Program by Neighborhood Socioeconomic Status*, JAMA, (June 17, 2022), https://jamanetwork.com/journals/jama-health-forum/fullarticle/2793530

[40] *Id.* (suggesting that economic opportunity cannot justify the disparity in the decline of 340B CPs in poor neighborhood because "the percentage of non-340B pharmacies in the same neighborhood *increased* by 1.3%").

[41] Ted Okon, STAT, *Hospitals and for-profit PBMs are diverting billions in 340B savings from patients in need*, (July 7, 2022), https://www.statnews.com/2022/07/07/for-profit-pbms-diverting-billions-340b-savings/

allowed for-profit CPs to expand their reach and charge fully insured patients at steep markups compared to the 340B discounts received and pocket the difference.[42] In reality, for-profit 340B CPs are not seeking to deliver charity care or serve disadvantaged populations; they are simply trying to maximize their profits.

ARGUMENTS

I. The Lack of Regulation Regarding the Exponential Growth of CPs Has Allowed PBMs to Profit Off of 340B

"The enormous growth in 340B contract pharmacy arrangements seems to boil down to a *single* factor: *outsized profit margins*."[43] And HRSA's lack of virtually any oversight on use of CPs by CEs has allowed PBMs to exploit 340B and retain a disproportionate share of these "outsized profit margins." Ironically, the exponential growth of CPs owned or affiliated with PBMs has shifted the recipients of 340B's substantial drug discounts from patients and CEs to some of the largest and most profitable healthcare companies.

A. PBM-Owned or Affiliated Pharmacies Comprise a Disproportionate Share of 340B CPs

The CPs participating in 340B are primarily not independent pharmacies. Rather, the vast majority of CP arrangements are between CEs and large for-profit pharmacies that are owned by or affiliated with the largest PBMs.[44] 340B has mutated to such an

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[42] *Id.*

[43] *Id.* (emphasis added).

[44] Karen Mulligan, PhD, University of Southern California, *The 340B Drug Pricing Program: Background, Ongoing Challenges and Recent Developments*, (Oct. 14, 2021) at 4, https://healthpolicy.usc.edu/wp-content/uploads/2021/10/The_340B_Drug_

extent that multi-billion-dollar, for-profit, publicly traded corporations dominate the 340B CP market.

The top five corporations controlling 340B CP relationships—CVS Health, Walgreens, Cigna, UnitedHealth Group and Walmart—now control 73% of all CP relationships.[45] Each of these entities also operate or are affiliated with a PBM. The three largest PBMs (Caremark, ESI and OptumRx), controlling 80% of the total prescription drug market account for 39% of all CP relationships through their owned or affiliated CPs.[46] In 2021, Walgreens and CVS held the greatest 340B CP market share with Walgreens controlling 31% of all retail CPs (up from 28% in 2020) and CVS controlling 19% of all retail CPs (up from 20% in 2020).[47] More than 80% of Walgreens retail pharmacy locations and two-thirds of CVS locations are CPs.[48]

Pricing_Program.pdf (noting that "[l]arge retail pharmacy chains—Walgreens, CVS, Walmart, and Rite Aid are disproportionately represented among contract pharmacies"); *see also* GAO 2018, at 21-22; (noting 75% of CP arrangements are held by "chain pharmacies").

[45] Adam Fein & Doug Long, *The Specialty Pharmacy Industry Update and Outlook*, May 3, 2022, https://drugch.nl/asembia22; *see also* 2018 GAO Rep., at 20-21 (noting approximately 75% of 340B CPs are chain pharmacies, notwithstanding that chain pharmacies represent scarcely half of all pharmacies nationwide).

[46] *Id.*

[47] Nephron ("Nephron"), *Decade-Long 34B Tailwind Gives Way to Significant Pharmacy Headwind in 1Q 2022*, at 9-10; *see also* Mulligan, at 4.

[48] Fein, DC, *Exclusive: 340B Continues Its Unbridled Takeover of Pharmacies and PBMs*, https://www.drugchannels.net/2021/06/exclusive-340b-continues-its-unbridled.html

Also noteworthy, in 2022, the three largest PBMs—Caremark, ESI and OptumRx—collectively own 500 mail order, specialty, and infusion pharmacies CPs.[49] Demonstrating the control CPs owned by PBMs have over the overall 340B CP market, these 500 CPs have a combined 35,000 arrangements with CEs.[50] These 500 mail, specialty, and infusion pharmacies owned by or affiliated with the three largest PBMs account for only 1.5% of all 340B CP *locations*, but 21% of the total 340B CP *relationships* with CEs.[51] And their control over these channels continues to rapidly increase. As of 2020, there were 16,293 CP arrangements between CEs and vertically integrated specialty pharmacies, representing a 1,006% growth from 2016.[52] CVS controls the largest share of specialty CPs, with 30.1% of the market.[53]

B. PBM Owned or Affiliated CPs Siphon Substantial Amounts of the 340B Financial Benefits Away from Covered Entities and the Patients They Serve

A lack of regulation over the growth and use of PBM owed and affiliated CPs has allowed for-profit corporations to exploit 340B and divert the financial benefits

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[49] Fein, DC, *Exclusive: Five Pharmacy Chains and PBMs Dominate 2022's Still Booming Contract Pharmacy Market*, https://www.drugchannels.net/2022/07/exclusive-five-pharmacies-and-pbms.html

[50] *Id.*

[51] *Id.*

[52] Vandervelde, at 4 (Oct. 2020), https://bit.ly/36X0eUG; Fein, DC, *PBM-Owned Specialty Pharmacies Expand Their Role In-and Profits From-the 340B Program*, https://www.drugchannels.net/2020/07/pbm-owned-specialty-pharmacies-expand.html

[53] Nephron, at 10.

intended for patients in need and the CEs that serve them.[54] In other words, the exponential growth of CPs has not translated into increased financial assistance for patients in need, but instead has served to create a new and very lucrative source of profits for large corporations.

i. PBM Owned or Affiliated CPs Are Estimated to Retain at Least $2.58 Billion of 340B Drug Discounts in 2022

In 2021, Walgreens CPs retained $994 million of 340B drug discounts, ESI CPs retained $561 million and OptumRx CPs retained $281 million.[55] Collectively, in 2022, Walgreens, Caremark, ESI and OptumRx are conservatively estimated to retain upwards of $2.58 billion in 340B discounts.[56] This is no small matter. If these corporations retain these discounts as profit, which is likely considering the CE supplies 340B drugs to the CP at essentially no cost to the CP, it would equate to between 6.4% to 17.4% of their adjusted operating profit.[57] However, the lack of transparency surrounding the financial relationships between CEs and CPs adds a degree of

[54] PhRMA, PR Newswire, *New Analysis Shows Contract Pharmacies Financially Gain From 340B Program With No Clear Benefit to Patients*, https://www.prnewswire.com/news-releases/new-analysis-shows-contract-pharmacies-financially-gain-from-340b-program-with-no-clear-benefit-to-patients-301148590.html ("It is clear that contract pharmacies have levered market power to drive unprecedented program growth and siphon money out of the program and away from vulnerable patients").
[55] Nephron, at 8-12.
[56] *Id.*
[57] *Id.*

uncertainty to these retention estimates.[58] In effect, the largest CPs (PBM owned or affiliated) are using 340B to fund their own for-profit operations, rather than to benefit CEs and the underserved communities they serve.

ii. PBMs and CPs Have Indicated that Reductions to Their 340B CP Footprint Would Significantly and Materially Affect Overall Profitability

340B has become a significant profit center for for-profit corporations owning PBMs and CPs. The annual reports of CVS Health and Walgreens Boots Alliance confirm that 340B profits are material to their business operations and warn that restrictive CP policies enacted by drug manufacturers, such as AstraZeneca, will negatively impact their bottom lines. *See e.g.*, CVS Health Corporation, Form 10-K FY 2021, p. 22-23 ("[a] reduction in 'Covered Entities' participation in contract pharmacy arrangements, as a result of the pending enforcement actions or otherwise, a reduction in the use of [CVS Health's] administrative services by Covered Entities, or a reduction in drug manufacturers' participation in the program could materially and adversely affect [CVS Health]"; WBA, Form 10-K FY 2021, p. 22 ("[c]hanges in pharmaceutical manufacturers' pricing or distribution policies and practices as well as applicable government regulations, including, for example, in connection with the federal 340B

[58] *See* BRG, *340B Program at a Glance* (estimating that "$10B in 340B profits [will be] captured by for-profit contract pharmacies in 2022."), https://media.thinkbrg.com/wp-content/uploads/2021/12/09062840/340B_Forecast-Report-Infographic_2021.pdf .

drug pricing program, could also significantly reduce [WBA's] profitability.")[59] Furthermore, OptumRx, which has lagged others in exploiting 340B, is advertising for a Director of 340B Business Opportunities.[60] Clearly, with the huge increase in CPs, 340B has mutated away from the original intention of Congress, to serve communities and patients in need, to increasing profits for large corporations.

C. PBMs Use Their Market Leverage to Optimize 340B Profits

The top PBMs use their huge market leverage to optimize the enormous profit potential of 340B.

i. PBMs Exclude CE-Owned CPs from Their Networks, Including Specialty Networks, While Simultaneously "Offering" to Serve as the CE's CPs

Many CEs have now opened their own in-house pharmacies. Naturally, these CEs seek to send their patients to their own in-house pharmacy, rather than a CP that could be hundreds or even thousands of miles away in the case of a mail order pharmacy.

Seeking to retain the 340B discounts it otherwise would have realized through use of their own CPs, PBMs have excluded CE-owned CPs from their networks.[61] Rather than permit the CE to dispense drugs to 340B eligible patients, PBMs restrict patients to only "in-network" pharmacies, ostensibly that they own or are affiliated

[59] Nephron, at 9 ("Walgreens is by far the most exposed to 340B, given long dominance in contract pharmacy, TPA, and tech services to covered entities").

[60] https://www.linkedin.com/jobs/search/?currentJobId=3062077478&keywords=optumrx%20director%20business%20development

[61] Jeffrey Lewis et al., *PBMs and the 340B Program*, https://340breport.com/wp-content/uploads/2021/06/PBMs-and-340B-White-Paper-June-29-2021.pdf.

with.[62] Using their enormous market leverage, the top PBMs also make aggressive offers to become CPs for the excluded CE and seek to coerce CEs to send their patients to a PBM owned or affiliated CP, in order to ensure that the PBM CP captures the 340B profits. This scenario could not be more contradictory to the intent and purpose of 340B.

ii. PBMs Mandate CEs Use a PBM Owned or Affiliated TPA that Retains a Percentage of 340B Discounts

Although use of CPs increases the potential distribution range for discounted drugs, it also greatly increases the complexity of determining 340B eligibility. To accurately determine which prescriptions are 340B eligible, many CEs, who are responsible for 340B compliance, contract with TPAs to retroactively reconcile which of the CE's claims are 340B-qualified.[63]

As discussed above, many of the largest 340B CPs are vertically integrated with TPAs. Consistent with their virtual stranglehold on the CP market, and motive to divert every 340B discount to themselves, TPAs vertically integrated with PBMs require CEs to contract with and use their own CPs. For example, beginning in 2018, CVS Health required CEs seeking to enter into a 340B CP arrangement with CVS to also utilize

[62] In fact, the House of Representatives has proposed a bill to prohibit PBMs from excluding certain contract pharmacies from their networks or engaging in discriminatory practices. *See* H.R. 4390, Protect 340B Act.
[63] 75 Fed. Reg. 10272, 10274-10278 (Mar. 5, 2010).

CVS Health's wholly owned TPA, Wellpartner, for 340B claim reconciliation.[64] CEs were presented with a choice: either use the PBM's TPA or not contract with CVS' vast network of CPs. CVS's Wellpartner now serves as the *exclusive* TPA for any CVS CP arrangement—accounting for 19% of all retail CPs and 30.1% of all specialty CPs.[65] Compounding this situation, Wellpartner charges CEs a percentage of each claim they reconcile. CVS has leveraged its market power and vertically integrated business model to monopolize significant portions of the 340B TPA market and to siphon a significant portion of 340B revenue for CVS' own benefit.

iii. PBMs Use 340B-Specific Pricing to Further Capture 340B Profits

When adjudicating pharmacy claims at the point-of-sale, PBMs require pharmacies, including CPs, to submit claims using electronic standards developed by the National Council for Prescription Drug Programs ("NCPDP"). Under current NCPDP protocols, a CP may identify a particular claim as 340B-eligible with a particular data entry in field 420-DK, called a "Submission Clarification Code."[66] Recently, several PBMs have sought to make the identification of 340B claims mandatory by 340B providers. ESI, for example, issued notice in February 2021 that CPs must

[64] *See RxStrategies, Inc. v. CVS Pharmacy, Inc.*, 390 F. Supp.3d 1341, 1347 (M.D.Fl. 2019) ("CVS now requires any covered entity that wants to fill 340B Program prescriptions at a CVS pharmacy to use Wellpartner as its program administrator. If the covered entity does not want to use Wellpartner as its 340B program administrator, it cannot utilize CVS as a contract pharmacy for the 340B program.").
[65] Nephron, at 10.
[66] A Submission Clarification Code of "20" identifies a claim as 340B-eligible.

retrospectively identify 340B claims.[67] Thereafter, PBMs (like ESI) began to impose significantly lower reimbursement rates for 340B claims, essentially usurping the savings that should have flowed to CEs, even when a PBM owned or affiliated pharmacy may not have been the CP.[68] In effect, PBMs are singling out 340B drugs for reduced reimbursement, "which essentially transfers the benefit of the program from safety net providers to for-profit payers."[69] PBMs have thus ensured that they profit from 340B in as many ways as possible.

II. The Profit Opportunities Presented by 340B and 340B CPs Have Incentivized PBMs to Drive Out Unaffiliated Providers to the Detriment of Patients

The substantial profit opportunities in 340B for CPs have further spurred PBM attempts to divert patient volume to their own affiliated CPs and drive unaffiliated CPs out of the market. PBMs have engaged in exclusionary tactics against unaffiliated providers participating in 340B; and for those unaffiliated providers able to obtain admission to these restrictive networks, PBMs actively seek to divert as much patient volume to their owned or affiliated pharmacies at every opportunity.

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[67] Rhiannon Klein, cv340b, *Express Scripts Issues 340B Claims Identification Requirements*, (Mar. 11, 2021, https://www.cv340b.org/express-scripts-issues-340b-claims-identification-requirements/

[68] Fein, DC, *How Hospitals and PBM Profit—and Patients Lose—From 340B Contract Pharmacies*, (July 23, 2022), https://www.drugchannels.net/2020/07/how-hospitals-and-pbms-profitand.html

[69] Legacy Health Endowment, *PBMs and the 340B Program*, at 1, https://340breport.com/wp-content/uploads/2021/06/PBMs-and-340B-White-Paper-June-29-2021.pdf

A. PBMs Engage in Exclusionary Tactics Against Unaffiliated Providers to Drive Business to PBM Owned CPs

PBMs engage in exclusionary tactics against unaffiliated and independent providers, including community oncology practices, by employing restrictive networks and overly burdensome admission requirements. In the specialty and mail order markets, PBMs have created both exclusive and near-exclusive networks whereby all PBM affiliated pharmacies are able to participate, but virtually no other pharmacy is permitted access.[70] Indeed, some PBM networks are effectively closed to any pharmacy unaffiliated with PBMs.[71] This is driven in large part by PBMs' quest to optimize 340B profits in as many ways as possible.

As noted above, specialty and mail order prescriptions account for a significant portion of 340B claims revenue. PBMs have made their specialty network application and approval process extremely onerous, and block admission to pharmacies failing to meet the PBMs' self-created and unachievable admission criteria.[72] When PBMs deny

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[70] Fein, DC, *The Top 15 Specialty Pharmacies of 2018: PBMs Keep Winning*, (Apr. 9, 2019), https://www.drugchannels.net/2019/04/the-top-15-specialty-pharmacies-of-2018.html*; see also* Frier Levitt, *Pharmacy Benefit Manager Exposé: How PBMs Adversely Impact Cancer Care While Profiting at the Expense of Patients, Providers, Employers and Taxpayers*, (Feb. 2022), https://communityoncology.org/wp-content/uploads/2022/02/COA_FL_PBM_Expose_2-2022.pdf

[71] *Id.*

[72] Jeffrey Lewis et al., PBMs and the 340B Program, https://340breport.com/wp-content/uploads/2021/06/PBMs-and-340B-White-Paper-June-29-2021.pdf.; Frier Levitt, *Pharmacy Benefit Manager Exposé: How PBMs Adversely Impact Cancer Care While Profiting at the Expense of Patients, Providers, Employers and Taxpayers*, (Feb. 2022), https://communityoncology.org/wp-content/uploads/2022/02/COA_FL_PBM_Expose_2-2022.pdf

unaffiliated pharmacy applications, they often require them to wait a year or more before they can reapply. PBMs require applying pharmacies to demonstrate a broad level of expertise in dispensing a wide range of specialty medications in numerous therapeutic classes.[73] Yet, without being admitted to PBM specialty networks, pharmacies have virtually no patients to dispense these specialty medications. The PBMs have created a sham application and admission process that, in all practicality, only allows their affiliated pharmacies to participate.[74]

Again, this is all by strategic design. By creating narrow networks where they are the only provider, PBM CPs ensure that they capture the vast majority of lucrative 340B prescriptions.

B. PBMs Engage in Patient Slamming and Prescription Trolling on an Individual Claims Level to Obtain 340B Prescriptions

Even when an unaffiliated provider gains access to a PBM's network, PBMs continue to leverage their market power to drive patients away from unaffiliated pharmacies, including community oncology practices, and towards their own CPs. For example, PBMs inappropriately utilize patient information and data received during claim submission to divert prescriptions towards their own CPs. When a PBM receives a patient's information from an unaffiliated pharmacy provider through the claim submission and/or prior authorization process, the PBM will transmit this information

[73] *Id.*
[74] *Id.*

to its own affiliated pharmacy to redirect the patient/prescription.[75] This is done without the explicit knowledge or consent of the patient. These PBM tactics are colloquially referred to as "prescription trolling," "patient slamming," and "claim hijacking"[76] and are especially pronounced in dealing with expensive specialty medications or lucrative mail order services.

C. Mandatory "White Bagging" Allows PBM CPs to Optimize 340B Profits

Another manipulative practice aimed at 340B profits engaged in by PBMs is mandated "white bagging," which is the distribution of infusible drugs, such as chemotherapy, direct to the provider for administration to the patient. Typically, these physician-administered drugs are purchased and stored at the site-of-care for administration under physician supervision. By the PBM mandating that it purchases the drug and ships to the physician from its specialty CP, the PBM is able to realize additional 340B profits beyond oral medications. A key distinction in "white bagging" is that prescriptions for these infusible drugs are not only now filled by a PBM CP (as

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[75] Community Oncology Alliance, *The Real-Life Patient Impact of PBMs: Volume I*, (April 1, 2017), https://communityoncology.org/study/the-real-life-patient-impact-of-pbms-volume-i/ (documenting instances where PBMs blatantly lied to patients and pharmacy staff, alleging the prescribing physician had authorized a transfer of the prescription, when in fact, they had not).

[76] *See* Frier Levitt, *Pharmacy Benefit Manager Exposé: How PBMs Adversely Impact Cancer Care While Profiting at the Expense of Patients, Providers, Employers and Taxpayers*, (Feb. 2022), https://communityoncology.org/wp-content/uploads/2022/02/COA_FL_PBM_Expose_2-2022.pdf (describing in detail the various forms of patient steering and its impact on patients, payers and providers).

opposed to purchased by the physician's office) but are also billed to the PBM through the pharmacy benefit.

From a clinical perspective, "white bagging" results in treatment delays, mistakes, waste, and administrative nightmares for practices.[77] However, PBMs are not monitored or regulated based on patients' clinical outcomes; they are motivated and rewarded by maximizing output from their 340B CPs. Contributing to the explosive growth of CPs, PBMs have found every opportunity to profit from oral drugs, and now infusible drugs as they attempt to mandate "white bagging" from their owned or affiliated specialty CPs.

The Court needs to understand that PBMs' quest to maximize profits through use of 340B CPs have a myriad of negative impacts from adversely affecting patient treatment and care to fueling drug prices and costs for Americans. PBM mandates to use their mail order and specialty pharmacies for both oral and infusible drugs wreak havoc with patient care by creating unnecessary treatment delays, denials, and costly waste. Not only do patients in need not get access to 340B discounts due to PBMs diverting them, but the growth of 340B is fueling pharmaceutical list prices. If drug manufacturers are forced to give out increasing discounts to middlemen, they will account for these discounts in the list prices of their drugs.

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[77] Frier Levitt, *Emerging Trends in Payor-Mandated White Bagging*, (Jan. 6, 2021), https://www.frierlevitt.com/articles-publications/emerging-trends-in-payor-mandated-white-bagging/#:~:text=White%20Bagging.,patient%20in%20the%20clinical%20setting.

While "white bagging" is not necessarily new, the trend of payor-mandated "white bagging" has dramatically increased along with the consolidation of the pharmacy benefit landscape, the rise of expensive specialty drugs, and the explosion of PBM-owned CPs. PBMs have increasingly required that certain specialty medications be filled by PBM-owned or associated specialty pharmacies and then "white bagged" to the provider.[78] Indeed, a 2019 survey of infused therapies revealed that in physician-affiliated clinics, "11% of oncology and 43% of nononcology treatments were obtained via white bagging" and in hospital outpatient departments, "28% of oncology and 31% nononcology infusions were from white bagging." [79] Recently, several PBMs (who have integrated specialty pharmacies) have made "white bagging" mandatory for certain specialty medications.[80]

The lure of 340B profits has accelerated this phenomenon. Whereas before, PBMs were largely unable to tap into office-administered medications that were purchased and stored at the site-of-care by providers, mandatory "white bagging" forces

[78] Marwood Group, *Pharmacy White Bagging: Growth And Countermeasures*, (Nov. 24, 2021), https://www.marwoodgroup.com/wp-content/uploads/2021/11/White-Bagging-Whitepaper-11_24_2021.pdf

[79] Deborah Abrams Kaplan, Managed Healthcare Executive, *How 'White Bagging' Affects Patients, Physicians and 340B Funding*, Vol. 1, Issue 2, (Feb. 18, 2021).

[80] Fein, DC, *White Bagging Update: PBMs' Specialty Pharmacies Keep Gaining on Buy-and-Bill Oncology Channels*, https://www.drugchannels.net/2021/10/white-bagging-update-pbms-specialty.html; *see also* Marwood Group, *Pharmacy White Bagging: Growth And Countermeasures*, (Nov. 24, 2021), https://www.marwoodgroup.com/wp-content/uploads/2021/11/White-Bagging-Whitepaper-11_24_2021.pdf (detailing the white bagging policies of the nation's largest health insurers).

these products into the pharmacy channel, and ostensibly, directs them to PBM-owned CPs. In the case of 340B claims, "white bagging" allows the PBM to control the distribution of 340B eligible drugs, which "undermine[s] the intent of 340B to allow hospitals to use savings from discounted drugs to improve access to care for the vulnerable communities they serve."[81] PBMs are especially motivated to mandate "white bagging" of oncology and other expensive infusible drugs given the substantial discounts afforded by 340B. Self-referrals to PBM-owned of affiliated specialty pharmacies "allows the insurance industry to retain the associated revenue, take advantage of rebates from pharmaceutical [manufacturers], and negotiate to obtain part of the 340B savings for eligible entities."[82]

[81] American Hospital Association, *Health Insurer Specialty Pharmacy Policies Threaten Patient Quality of Care*, (Mar. 2021), at 2, https://www.aha.org/system/files/media/file/2021/03/AOMarch8white-bagging-0221.pdf

[82] Brandy Snyder et al., HOPA News, *An Overview of White Bagging: The Effect on Systems and Potential Strategies*, Hemotology/Oncology Pharmacy Association, Vol. 18, Issue 3, at 8, https://www.hoparx.org/hopa-news/volume-18-issue-3-2021/all-pages

This practice, which has had documented instances of increased waste to plan sponsors[83] and harm to patients,[84] is fueled by PBMs' desire to divert more drugs through their own CPs, thus optimizing their profits from 340B.

III. CONCLUSION

Given the unregulated and unchecked growth of for-profit CPs participating in 340B that are owned by or affiliated with vertically integrated PBMs, and the mounting evidence that these entities are siphoning substantial portions of 340B drug discounts, warping the original congressional-intended purpose of 340B, *amicus* Community Oncology Alliance, Inc. supports Plaintiff-Appellee AstraZeneca Pharmaceuticals, LP and the District Court's ruling granting in part their motion for summary judgement and vacating HHS's Enforcement Letter.

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[83] Deborah Abrams Kaplan, Managed Healthcare Executive, *How 'White-Bagging' Affects Patients, Physicians and 340B Funding*, Vol. 31, Issue 2, (Feb. 18, 2021); Frier Levitt, *Pharmacy Benefit Manager Exposé: How PBMs Adversely Impact Cancer Care While Profiting at the Expense of Patients, Providers, Employers and Taxpayers*, (Feb. 2022), https://communityoncology.org/wp-content/uploads/2022/02/COA_FL_PBM_Expose_2-2022.pdf

[84] *Id.*; AHA, *Health Insurer Specialty pharmacy Policies Threaten Patient Care,* https://www.aha.org/white-papers/2021-03-08-health-insurer-specialty-pharmacy-policies-threaten-patient-quality-care.

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