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Thank you, Chairman Arnold and Chairman Lewis, and members of CANN's 340B Committee. My name is Adam Fein. I appreciate the opportunity to present my views about the federal 340B Drug Pricing Program.

The 340B program is highly controversial, in part because its founding legislation did not specify or restrict how covered entities should utilize the funds that the program generates. Notably, covered entities are not specifically obligated to share any 340B savings with financially needy or uninsured patents, nor are they required to disclose how they use profits from the 340B program.

I will focus on **contract pharmacies**—the external pharmacies that are a little understood but rapidly growing part of the 340B program. Covered entities increasingly rely on external pharmacies to extend 340B pricing to a broad set of patients. As I document below, nearly one in four retail, mail, and specialty pharmacies acts as a contract pharmacy for hospitals and other healthcare providers that participate in the 340B Drug Pricing Program. Covered entities are not prohibited from sharing 340B program savings with external pharmacies.

In my opinion, the unmanaged and unexpected growth of contract pharmacies is causing significant channel distortions within the U.S. pharmaceutical distribution and reimbursement system. As I will explain, these distortions include:

- Raising out-of-pocket costs for uninsured patients
- Curbing manufacturers' willingness to offer rebates to Medicare Part D and commercial payers
- Permitting pharmacies to profit from 340B discounts at the expense of needy and uninsured patients
- Lowering the generic drug dispensing rate

I conclude with a set of policy recommendations for the contract pharmacy program.

First, a few words about my industry experience and knowledge of these issues. I am an expert in the complex economic interactions within the U.S. pharmacy distribution and reimbursement system. I earned my Ph.D. in Managerial Science and Applied Economics from the Wharton School of Business at the University of Pennsylvania. As president of Pembroke Consulting, Inc., a management consulting and research firm based in Philadelphia, I advise executives at the country's leading pharmaceutical manufacturers on how to improve their commercial strategies. Through Pembroke's Drug Channels Institute, I write the influential Drug Channels website. There, I analyze news and research related to pharmaceutical economics and the drug distribution system. I also write and publish detailed annual industry reports on the economics of pharmacies, wholesalers, and pharmacy benefit managers (PBMs).

I. MARKET OBSERVATIONS

Below are the results of our research into the 340B programs and contract pharmacies.

1) The 340B Drug Pricing Program is a growing part of the U.S. pharmaceutical market.

The 340B program was created by Section 602 of the Veterans Health Care Act of 1992 (P.L. 102-585), which established Section 340B of the Public Health Service Act. The Health Resources and Services Administration (HRSA), an agency of the U.S. Department of Health and Human Services, manages the program through its Office of Pharmacy Affairs (OPA).

The 340B program mandates that pharmaceutical manufacturers provide outpatient drugs to certain healthcare entities—known as eligible covered entities—at significant discounts. To be eligible for program participation, providers must be one of six designated hospital types or be an entity that receives federal grants administered by different agencies within HHS. Hospitals must meet additional eligibility criteria that vary by hospital type.

Pharmaceutical manufacturers agree to charge a 340B ceiling price to covered entities by signing a Pharmaceutical Pricing Agreement (PPA) with the Secretary of Health and Human Services. Manufacturers that participate in the Medicaid Drug Rebate Program must sign a PPA.

The 340B program has grown to account for at least 6% of the total U.S. drug market. According to data provided to me by HRSA, discounted purchases made under the program via Apexus, the HRSA-designated Prime Vendor, totaled $19.3 billion in 2017.[1] What's more, I have found that since 2014, purchases under the program have grown at an average rate of 29% per year. Over the same period, manufacturers' net drug sales have grown at an average annual rate of less than 5%.

2) Since 2010, covered entities have significantly expanded their use of contract pharmacies.

A covered entity can purchase and dispense 340B drugs through internal and external (contract) pharmacies. In 2010, HRSA permitted eligible entities (including those that have an in-house pharmacy) to access 340B pricing through multiple contract pharmacies.[2]

Since this change in guidance, the number of contract pharmacies has increased sharply.

- In 2010, there were fewer than 1,300 contract pharmacies.[3]

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[1] Fein, Adam J., EXCLUSIVE: The 340B Program Reached $19.3 Billion in 2017—As Hospitals' Charity Care Has Dropped, *Drug Channels*, May 2018.
[2] Health Resources and Services Administration, Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, *Federal Register*, March 5, 2010.
[3] U.S. Government Accountability Office, Status of Agency Efforts to Improve 340B Program Oversight, May 15, 2018.

- By mid-2017, we counted 19,868 unique pharmacy locations, a figure that amounts to nearly one in four U.S. retail, mail, long-term care, and specialty pharmacy locations.[4]

- The almost 20,000 unique pharmacy locations have broad and deep relationships with providers. As of mid-2017, there were 6,059 340B covered entities with 52,613 contract pharmacy relationships. Since 2013, the number of 340B contract pharmacy relationships has increased by 66%.

3) Large, for-profit pharmacy chains are the primary operators of contract pharmacies.

Six large retail chains account for two thirds of 340B contract pharmacy locations. These companies have dominated contract pharmacies for a few years now.

- Walgreens remains the most active 340B contract pharmacy participant. More than 6,300 Walgreens locations act as 340B contract pharmacies, and the chain accounts for more than one-third of all locations.

- Other major retail chains—CVS, Walmart, Rite Aid, Kroger, and Albertsons—account for an additional 6,877 contract pharmacy locations.[5]

- In line with overall program growth, the largest chains have dramatically increased the number of locations acting as 340B contract pharmacies. This implies that the profits have been substantial enough to justify this expansion.

- Central-fill mail and specialty pharmacies have become much more significant industry participants. For instance, four Walgreens' specialty pharmacy locations act as a contract pharmacy for more than 250 340B covered entities.

4) Some covered entities have established contract pharmacy mega-networks.

Many covered entities have relatively small 340B contract pharmacy networks. However, some have built large networks. Our research has uncovered the following facts about these networks.[6]

- About 4,900 340B covered entities with contract pharmacies have small networks of fewer than 10 pharmacies.

- About 1,000 providers have networks with 11 to 50 pharmacies, accounting for 45% of contract pharmacy arrangements.

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[4] Fein, Adam J., The Booming 340B Contract Pharmacy Profits of Walgreens, CVS, Rite Aid, and Walmart, *Drug Channels*, July 2017.

[5] Since our 2017 analysis, Rite Aid has sold more than 1,900 of its pharmacy locations to Walgreens and announced a merger with Albertsons.

[6] Fein, Adam J., 10 Hospitals With 340B Contract Pharmacy Mega-Networks, *Drug Channels*, July 2017.

- A small group of 156 healthcare providers (2.6% of covered entities with contract pharmacies) account for more than one-quarter of all contract pharmacy relationships. These providers have built networks averaging 89 pharmacies. Of the 156, 98 are disproportionate share hospitals (DSH).

- The 10 DSH entities with the largest 340B contract pharmacy networks collectively account for 2,267 (4.3%) of the total 52,613 contract pharmacy relationships. Each hospital's network has an average of 227 pharmacies.

We do not know whether covered entities need such large networks to reach their vulnerable patient populations. These networks are seemingly designed to enrich certain covered entities and pharmacies, not to help needy and uninsured patients. Covered entities are not required to justify such large networks on the basis of access needs for uninsured, underinsured, and needy populations. We also have limited information about how 340B entities monitor such large networks, nor do we know how or if they monitor out-of-state mail and specialty pharmacies.

II. CHANNEL DISTORTIONS FROM 340B CONTRACT PHARMACIES

I believe that the growing use of contract pharmacies leads to at least four significant problems in the U.S. drug distribution and reimbursement system. I outlined some of these issues in a peer-reviewed article published in 2016.[7]

1) Needy patients may not benefit from prescriptions filled at contract pharmacies.

There is evidence that uninsured and indigent patients do not always benefit from 340B drug discounts earned from third-party or patient paid prescriptions dispensed by contract pharmacies.

The small amount of public information about the operation of 340B contract pharmacy arrangements paints a dismal picture for uninsured patients. The Office of Inspector General (OIG) has published only one study of contract pharmacies. [8] It found that 5 out of the study's 15 hospitals offered uninsured patients the 340B discount prescription price. The other 10 hospitals' contract pharmacies required uninsured patients to pay the full, non-340B price, even though hospitals were purchasing the drugs at the deeply discounted 340B price. By contrast, thirteen of the study's community health centers reported offering the discounted 340B price to uninsured patients in at least one of their contract pharmacy arrangements.

These problems stem partly from the ways in which covered entities manage contract pharmacy relationships. Covered entities and their software vendors classify outpatient prescriptions as "340B eligible." They do this via non-public processes that are not subject to formal regulations.

[7] Fein, Adam J., Challenges for Managed Care from 340B Contract Pharmacies, *Journal of Managed Care and Specialty Pharmacy*, March 2016.
[8] Office of Inspector General, Contract Pharmacy Arrangements in the 340B Program, OEI-05-13-00431IG, February 4, 2014.

Due to the lack of regulations, different entities have different standards for identifying 340B-eligible prescriptions. The OIG has described four common scenarios that would result in differing determinations of 340B eligibility across covered entities.[9] The OIG notes that "two covered entities may categorize similar types of prescriptions differently, i.e., 340B-eligible versus not 340B-eligible, in their contract pharmacy arrangements."

In a separate report, the Government Accountability Office (GAO) noted, "[S]ome covered entities may be broadly interpreting the definition to include individuals such as those seen by providers who are only loosely affiliated with a covered entity and thus, for whom the entity is serving an administrative function and does not actually have the responsibility for care."[10]

In a forthcoming report, the Government Accountability Office (GAO) plans to provide additional details about the extent to which selected covered entities provide discounts on 340B drugs dispensed by contract pharmacies to low-income, uninsured patients.[11]

2) Manufacturers have incentives to reduce rebates to Medicare Part D and commercial payers.

Manufacturers cannot identify 340B prescriptions dispensed by contract pharmacies. In my opinion, manufacturers therefore offer smaller formulary rebates to Part D plans and commercial payers so as to offset potential paying duplicate discounts on these claims. As 340B contract pharmacies penetrate retail networks, managed care organizations may receive lower formulary rebates from manufacturers and incur higher net pharmacy benefit reimbursement expenses.

The 340B statute prohibits manufacturers from having to provide a discounted 340B price and a Medicaid drug rebate for the same drug. Covered entities are required to follow HRSA rules to prevent such "duplicate discounts."[12] The prohibition on duplicate discounts applies to traditional Medicaid arrangements as well as Medicaid programs operated by managed care organizations, also known as Managed Medicaid.

However, it can be difficult to identify prescriptions for Managed Medicaid beneficiaries in contract pharmacy arrangements. Administrators of 340B contract pharmacy programs cite insufficient information from state Medicaid agencies and plan identifiers that are not exclusive to Medicaid.[13] Consequently, pharmaceutical manufactures may be inappropriately paying duplicate discounts on these Medicaid prescriptions. There are no public data to document the extent of this problem.

Unlike the provisions in Medicaid, there are no statutory protections for prescriptions paid by commercial third-party payers or Medicare Part D plans. Unless manufacturers and managed care

[9] Office of Inspector General, Contract Pharmacy Arrangements in the 340B Program, OEI-05-13-00431IG. February 4, 2014.
[10] U.S. Government Accountability Office, Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement, September 2011.
[11] U.S. Government Accountability Office, Status of Agency Efforts to Improve 340B Program Oversight, May 15, 2018.
[12] Health Resources and Services Administration, Medicaid Exclusion/Duplicate Discount Prohibition.
[13] Office of Inspector General, Contract Pharmacy Arrangements in the 340B Program, OEI-05-13-00431IG, February 4, 2014.

organizations (MCO) negotiate contract language prohibiting duplicate discounts, manufacturers will also pay rebates on the same prescriptions to commercial payers for products that covered entities purchase at 340B prices. Neither MCOs nor manufacturers can readily identify which prescriptions have been dispensed to 340B patients. Since 340B-eligible prescriptions are typically not identified until after the claim has been processed, pharmacies generally do not know whether or not a prescription relates to the 340B program.

The National Council for Prescription Drug Programs (NCPDP), which sets electronic communication standards for pharmacy care, allows the identification of an individual prescription's status under the 340B Drug Pricing Program.[14] However, most hospitals and contract pharmacies do not regularly utilize this voluntary standard. Some 340B advocates have argued that it is impossible for pharmacies to comply with such standards, because a pharmacy would have to reverse and resubmit each 340B claim.[15] Manufacturers would be justified in reducing managed care formulary rebates based on presumed 340B-dispensed claims.

3) External contract pharmacies may be profiting inappropriately from 340B discounts.

By using contract pharmacies, a 340B entity profits from prescriptions filled by a retail or mail network pharmacy—after the prescription has been adjudicated and paid by a third-party payer. The covered entity profits from the difference between a pharmacy's third-party reimbursement (minus fees to the contract pharmacy and software vendor) and the 340B acquisition cost.

Rather than earning traditional dispensing spreads and fees, 340B contract pharmacies earn per-prescription fees paid by the 340B entity. These fees can include fixed dollar payments as well as revenue-sharing and profit-sharing arrangements. We estimate that these arrangements can also be much more profitable for pharmacies than are typical third-party margins. Thus, the pharmacy trades its normal profit margin for the contract pharmacy payments.

Given substantial profit opportunities, a covered entity can afford fees that often exceed a pharmacy's typical profits from dispensing a third-party-paid prescription. This profitability enables covered entities to offer—and pharmacies to demand—generous pharmacy fees and in some cases share a percentage of the prescription savings with the contract pharmacy. I am aware of contractual agreements that compensate the 340B contract pharmacy at four or more times the pharmacy's typical prescription profit margin.

4) The 340B program appears to be reducing the use of generic drugs.

Covered entities' profits from 340B prescriptions may be reducing generic dispensing rates, which would raise costs for third-party payers. For covered entities, the greatest 340B purchase discounts come from

[14] National Council for Prescription Drug Programs, 34ØB Information Exchange, Reference Guide Version 1.Ø. July 2011.
[15] Letter from Safety Net Hospitals for Pharmaceutical Access (SNHPA) to Jason A. Helgerson, Medicaid Director and Deputy Commissioner, New York State Department of Health, December 19, 2011.

brand-name drugs. This can encourage the 340B entity to prescribe brand-name drugs when equivalent generic alternatives exist.

Consistent with this supposition, the only published study of contract pharmacy dispensing activity found that the generic dispensing rate was statistically significantly lower for 340B prescriptions when compared with all prescriptions.[16]

The substitution of less-expensive generic drugs for brand-name drugs is a significant factor behind slowing growth in pharmacy spending. Third-party payers face the risk of increased costs when a contract pharmacy negotiates a fee arrangement based on 340B revenues or profits. Given substantial profit opportunities, a 340B entity can often afford fees that exceed a pharmacy's typical gross profit from dispensing a third-party-paid prescription. There are no public data available to analyze generic dispensing rates for 340B eligible prescriptions and assess this risk.

III. POLICY RECOMMENDATIONS FOR 340B CONTRACT PHARMACIES

- **Mandate that contract pharmacies for 340B covered entities charge no more than the discounted 340B price to uninsured, underinsured, and vulnerable patients.**

- **Require contract pharmacies to identify 340B prescriptions at the time of adjudication (payer prescription approval).** This change would make manufacturers more willing to offer larger rebates to third-party payers.

- **Require greater transparency as well as the disclosure of fees and profits generated by 340B contract pharmacies.** Such a requirement would ensure that discounts provided under the 340B program are being utilized appropriately.

- **Require that contract pharmacy fees be based on fair market value standards.** This would prevent for-profit pharmacies from capturing 340B discounts. It would also protect smaller covered entities that lack negotiating clout with the larger 340B contract pharmacy providers.

- **Limit the number and geographic scope of contract pharmacy arrangements.** Covered entities are not required to justify large networks on the basis of access needs for vulnerable populations. As an AIR340B report sensibly recommended: "Contract pharmacies should be located where vulnerable patients qualifying for assistance live, rather than in distant communities selected on the basis of how many people have insurance that can be billed at the largest margin above 340B-acquisition cost."[17]

[16] Clark BL, Hou J, Chou C-H, Huang ES, and Conti R, The 340B Discount Program: Outpatient Prescription Dispensing Patterns Through Contract Pharmacies In 2012. *Health Affairs*, 33, no.11 (2014):2012-2017.
[17] Berkeley Research Group, The Impact of Growth in 340B Contract Pharmacy Arrangements, Air340B, 2014.