NATIONAL ASSOCIATION OF
SPECIALTY PHARMACY

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Lina Khan
Chairperson
Federal Trade Commission
600 Pennsylvania Ave., N.W.
Washington, D.C. 20580

BY ELECTRONIC DELIVERY

RE: FTC Study on Pharmacy Benefit Managers' (PBMs) Relationship with Affiliated and Independent Pharmacies

Dear Chairperson Khan:

I write today on behalf of the National Association of Specialty Pharmacy (NASP) to express support and urgency in having the Federal Trade Commission proceed with a **Study on Pharmacy Benefit Managers' (PBMs) Relationship with Affiliated and Independent Pharmacies**. The FTC should vote this week in favor of issuing orders to large pharmacy benefit managers to study the competitive impact of: contractual provisions, reimbursement adjustments, and other practices, including those practices that disadvantage specialty pharmacies.

NASP represents the entire spectrum of specialty pharmacy industry stakeholders, including the nation's leading specialty pharmacies and practicing pharmacists; nurses; technicians; pharmacy students; non-clinical healthcare professionals and executives; pharmacy benefit managers (PBMs); pharmaceutical manufacturers; group purchasing organizations; wholesalers and distributors; integrated delivery systems and health plans; patient advocacy organizations; independent accreditation organizations; and technology, logistics and data management companies. With over 150 corporate members and 2000 individual members, NASP is the unified voice of specialty pharmacy in the United States.

What is Specialty Pharmacy

Specialty pharmacies support patients who have complex health conditions like rheumatoid arthritis, multiple sclerosis, hemophilia, cancer, organ transplantation and rare diseases. Specialty pharmacies operate as independent pharmacies, academic medical center and hospital-health system based pharmacies, regional and national chain pharmacies, grocery store owned specialty pharmacies and home infusion pharmacies. The medications a specialty

pharmacy dispenses are typically expensive. Historically, there are limited generic or biosimilar alternatives to brand specialty drugs. Specialty prescription medications are not routinely dispensed at a typical retail pharmacy because the medications are focused on a limited number of patients and require significant patient education and monitoring on utilization and adherence. Typical retail pharmacies are not designed to provide the intense and time-consuming patient care services that specialty medications require. Though many specialty medications are taken orally, still many need to be injected or infused. The services a specialty pharmacy provides includes patient training in how to administer the medications, comprehensive treatment assessment, ongoing patient monitoring, side effect management and mitigation and frequent communication and care coordination with caregivers, physicians and other healthcare providers. A specialty pharmacy's expert services drive patient adherence, proper management of medication dosing and side effects, and ensure costly and complex drug therapies and treatment regimens are used correctly and not wasted.

Concerns with Market Dominance and Impact on Specialty Pharmacy

While the number of specialty medications only comprises 2.2 percent of the total number of prescriptions dispensed in the United States, it represents approximately 50 percent of overall drug spend in the U.S., which by the end of 2021 was estimated to be about $600 billion. Distribution for most specialty medications is limited, with payers working to keep them even smaller. The market is heavily dominated by the largest PBMs and the health insurers that own those PBMs.

While the specialty market has grown, so has vertical integration in the market. The three largest PBMs—CVS Caremark (subsidiary of CVS Health, Inc.; 2019 revenue: $141.5 billion), Express Scripts (subsidiary of Cigna, Corp.; 2019 revenue: $96.4 billion), and OptumRx (subsidiary of UnitedHealth Group; 2019 revenue: $74.3 billion)—account for more than 80% of the PBM market.[1],[2] Insurers have more incentive to fill a specialty drug through their PBM-owned specialty pharmacy. The largest PBMs also dominate the specialty pharmacy market, having their own or an affiliation with three of the four largest specialty pharmacies in the United States: CVS Specialty (owned by CVS Health, Inc.), Accredo / Freedom Fertility (owned by Express Scripts), and Optum Specialty Pharmacy (owned by OptumRx).[3] The impact on pharmacy access for patients and cost to the overall health care system as vertical integration persists is dire. **Far more oversight by the FTC and the Department of Health and Human Services is necessary, and the FTC should also provide recommendations to Congress on statutory changes needed to ensure that: pharmacy networks include a robust network of specialty pharmacies for patients; the practice of patient steering is prohibited; and pharmacy DIR claw backs on pharmacies are eliminated and prohibited.**

[1] https://www.acpjournals.org/doi/abs/10.7326/M17-2506?journalCode=aim
[2] https://docs.house.gov/meetings/JU/JU05/20151117/104193/HHRG-114-JU05-Wstate-BaltoD-20151117.pdf
[3] https://www.drugchannels.net/2020/04/the-top-15-specialty-pharmacies-of-2019.html

Pharmacy Networks

In many instances, specialty pharmacies have witnessed increased efforts by PBMs to limit the participation of non-affiliated specialty pharmacies in a given pharmacy network. Tactics such as demanding impossible terms for participation and non-negotiable reimbursement rates that do not cover the cost of the drug alone – let alone the patient management and product support services needed to go with the drug - are all too common. Impossible terms can include requiring a specialty pharmacy to stock non-specialty drugs that are outside the needs of its patient base and mandating that a pharmacy set up additional physical locations despite the PBM knowing that specialty pharmacies have a hub and spoke model where they successfully ship medications to patients as opposed to operating multiple physical facilities. Specialty pharmacies must repeatedly work through state and federal laws and fight to get into provider networks. Examples of anti-competitive actions vertically integrated PBMs take to limit pharmacy network participation include the following:

- **Complex credentialing and staffing requirements**—Many PBM networks require in-network specialty pharmacies to be accredited by at least one of the independent accrediting bodies such as ACHC, NCQA, URAC or the Joint Commission. NASP supports independent national third-party accreditation as a tool to drive quality based on uniformly applied measures, standards and processes. However, many PBMs that also own a specialty pharmacy are requiring accreditation by their own PBM as a condition for network participation, despite a pharmacy being accredited by a third-party independent organization. In addition to charging a fee for this accreditation, the PBM-owned accreditation process includes a detailed audit of business processes, capturing photos and reviewing other proprietary and strategic documents all under the auspices of "network credentialing." Most of this entire process is not relevant at all for specialty pharmacies' ability to dispense drugs and take care of patients. Rather, specialty pharmacies claim it is an attempt to gather sensitive competitive business intelligence that will be used in an anti-competitive manner. In other words, there is very little confidence in the fire wall that is supposed to exist between the PBM and its own accreditation process.

- **Providing contract terms that under reimburse drugs—**PBM's offer drug reimbursement rates below the purchase price of specialty pharmacies. For example, many of the current Pharmacy Services Administration Organization contracts contain a take it or leave reimbursement rate that is below acquisition cost. This ability is driven by the PBM in its effort to favor its own specialty pharmacy that has either a better reimbursement rate given its size or can sustain the loss also because of its size and dominance in the marketplace.

- **Contracting specialty pharmacies as retail pharmacies—** PBMs typically contract specialty pharmacies as a retail pharmacy. The challenge is that specialty pharmacy is not a retail pharmacy and offers distinctly different drugs and services than a typical

retail pharmacy. Because PBMs also typically own their own mail order pharmacy, they will not offer a specialty pharmacy a contract that allows for delivery of medications to patients via the mail. While contracted as a retail pharmacy despite its difference in business model, a PBM can accuse the pharmacy of not meeting retail requirements, and when this occurs, a specialty pharmacy can be removed from the network. This same threat does not exist for a PBM-owned specialty pharmacy that equally dispenses the same amount of drug through the mail. Many of NASP's members have received notice or have been thrown out of network for violating the "mail order" clause of the retail contract.

Patient Steering

Far too often, even when pharmacies get into a network, large PBMs will work to capture a prescription away from a network pharmacy – a practice referred to as patient steering. Vertically integrated PBMs can see a patient's insurance information and will use the information to call or send a letter to a patient or prescriber, instructing them to transfer their prescription to the PBM-owned specialty pharmacy, or otherwise risk their drug's coverage. Extremely sick and vulnerable patients are threatened to lose their coverage for a drug they otherwise may not be able to afford or access if they do not comply with the PBM's demands. In other instances, a PBM will require a prior authorization from an in-network pharmacy but will waive the prior authorization if a patient uses a PBM-owned specialty pharmacy. While the prescription is "under review," the PBM-owned specialty pharmacy will sometimes fill and dispense the specialty drug, thereby essentially stealing the prescription from the independent specialty pharmacy.

Without federal oversight through such entities as the Federal Trade Commission or the HHS Office of Civil Rights, or the establishment of enforcement protections, network pharmacies continue to fall victim to these anti-competitive practices, and patient access to their pharmacies is suppressed.

Pharmacy DIR Fees

An anti-market practice contributing to high drug costs under Medicare Part D that requires immediate action by the Biden Administration and Congress is the reform of pharmacy direct and indirect remuneration fees – called pharmacy DIR fees. Pharmacy DIR fees are monies received by PBMs and Medicare Part D health plans that today include concessions pharmacies are forced by PBMs to pay long after the pharmacy dispenses medications to a Medicare beneficiary. These fees are not used by PBMs or their affiliated health plans to reduce the cost of the drugs for seniors. Pharmacy DIR fees only result in profit for PBMs/payers, forcing pharmacies to fill Medicare prescriptions below cost.

In January 2022, the Centers for Medicare and Medicaid Services (CMS) released a proposed rule for *Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and*

Medicare Prescription Drug Benefit Programs[4] that would make great progress through certain pharmacy direct and indirect remuneration (DIR) fee reform in Medicare Part D. In the proposed rule, CMS states that pharmacy DIR fees grew more than 107,400 percent between 2010 and 2020.[5] This immense growth requires an immediate review and examination by the FTC. Specialty pharmacies pay millions of dollars in DIR fees per year, with these fees assessed six months or longer after the pharmacy has dispensed the drug to a beneficiary and with no transparency as to what the fees represent. The net negative effect on market participation and competitiveness has been significant.

Medicare Part D prescription drug plan sponsors report pharmacy DIR to CMS within six months after the close of the plan year.[6] Based on publicly available data, CMS found that in recent years, plan sponsors have consistently received higher DIR than they initially estimated during the bidding process for contracting with the Medicare Part D program.[7] In other words, PBMs and plan sponsors have been underestimating DIR. This finding is important because it indicates that any DIR received by PBMs and plan sponsors above the projected amount factored into a plan's bid contributes primarily to plan profits, not lower premiums for Medicare beneficiaries.

Conclusion

NASP is pleased the FTC is discussing the need to examine these issues closely, and we ask that the FTC vote in favor of conducting the "Study on PBMs' Relationship with Affiliated and Independent Pharmacies," and do so without further delay. We need to ensure there is oversight over anti-market practices that are gravely limiting patient access to specialty pharmacies today. Policymakers and federal agencies also need recommendations and guidance from the FTC on areas for legislative and regulatory intervention that may be outside of the FTC's authority but that must be addressed to ensure market competitiveness and fairness.

NASP appreciates the opportunity to provide an oral statement and written comments for the FTC's consideration. If we can provide additional information, please contact me at

[4] 87 Fed. Reg. 1842.
[5] *Id.*
[6] https://fas.org/sgp/crs/misc/R40611.pdf
[7] https://www.govinfo.gov/content/pkg/FR-2017-11-28/pdf/2017-25068.pdf

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Respectfully submitted,

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