NATIONAL ASSOCIATION OF
SPECIALTY PHARMACY
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BY ELECTRONIC DELIVERY

Maureen Ohlhausen
Acting Chairman
Federal Trade Commission
400 7th Street SW
Washington DC 20024

Re: Understanding Competition in Prescription Drug Markets: Entry and Supply Chain Dynamics

Dear Ms. Ohlhausen:

The National Association of Specialty Pharmacy (NASP) appreciates this opportunity to submit comments to the Federal Trade Commission's (FTC) public workshop on "Understanding Competition in Prescription Drug Markets: Entry and Supply Chain Dynamics" (Workshop).[1] NASP is a non-profit trade organization and the only national association representing all stakeholders in the specialty pharmacy industry. NASP's mission is to elevate the practice of specialty pharmacy by developing and promoting continuing professional education and certification of specialty pharmacists while advocating for public policies that ensure patients have appropriate access to specialty medications in tandem with critical services.

NASP members include the nation's leading independent specialty pharmacies, pharmaceutical and biotechnology manufacturers, group purchasing organizations, patient advocacy groups, integrated delivery systems and health plans, technology and data management vendors, wholesalers/distributors and practicing pharmacists. With over 100 corporate members and 1,200 individual members, NASP is the unified voice of specialty pharmacy in the United States.

Our members are committed to refining the practice of specialty pharmacy with a single focus on the patients we serve to ensure better clinical outcomes while reducing overall healthcare costs. With this guiding principle, NASP is the leading education resource for specialty pharmacists. The association provides NASP University, an online education center offering 50 continuing pharmacy education programs, hosts an annual meeting that offers education sessions and continuing education credits, and is the only organization that offers a certification program for specialty pharmacists.

[1] https://www.ftc.gov/news-events/events-calendar/2017/11/understanding-competition-prescription-drug-markets-entry-supply

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As a result of our diverse membership and the wide range of services we provide, NASP offers a unique perspective on the current market dynamics in the distribution channel for specialty drugs and biologics and is pleased to provide our comments below.

I. Background:

NASP represents an industry that focuses on providing quality patient care first with an added emphasis on clinical outcomes and patient choice. It is these outcomes that drive competition amongst and between NASP members and is the principle metric on which each is judged. Because the strategic goals of the FTC are to protect consumers, maintain competition and advance organization performance[2], NASP's comments will also focus on those objectives in addition to addressing the questions presented for the Workshop. Specifically, NASP's members have encountered certain behaviors, as detailed below, by PBM's that own a specialty pharmacy that are contrary to the FTC's mission, which "is to protect consumers by preventing anticompetitive, deceptive, and unfair business practices."[3] NASP notes that PBM Market Share of the top 3 PBMs by prescription volume (ESI, CVS Caremark, OptumRx) is nearly 70 percent which clearly affords each of these entities significant market power over independent specialty pharmacies because each owns a specialty pharmacy.[4] NASP believes that the activities by the PBM that also owns a specialty pharmacy and contract provisions that each offers as detailed below prevent competition and significantly reduce consumer choice.

II. PBMs That Own a Specialty Pharmacy Have Had a Dramatic Impact on Patient Access and Consolidation has Also Negatively Impacted Access

Initially, NASP addresses the FTC's third question presented at the Workshop that focuses on the role of certain intermediaries in the distribution channel. Specifically, the FTC is interested in understanding the role that PBMs and GPOs "play in prescription drug pricing, consumer access, and quality. What are the benefits and costs of intermediaries in the pharmaceutical supply chain? Has consolidation affected price, access, or quality?"[5] In order to answer this question, NASP first details the important role that specialty pharmacies have in the distribution channel as it relates to caring for patients and the competition it faces with PBM owned specialty pharmacies.

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[2] https://www.ftc.gov/about-ftc
[3] https://www.ftc.gov/about-ftc
[4] The CVS-Aetna Deal: Five Industry and Drug Channel Implications, http://www.drugchannels.net/2016/01/solving-mystery-of-employer-pbm-rebate.html (accessed 12/5/2017),
[5] https://www.ftc.gov/news-events/events-calendar/2017/11/understanding-competition-prescription-drug-markets-entry-supply

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As discussed at the Workshop, specialty pharmacies typically purchase specialty drugs from either a wholesaler or directly from the manufacturer. The terms of this initial transaction can vary between specialty pharmacies depending on the patient population that the specialty pharmacy serves and other market factors. In other words, there is a private sector negotiation that takes place between two commercial entities that being the specialty pharmacy and the manufacturer/wholesaler.

Once the specialty pharmacy takes title of the drug from the manufacturer/ wholesaler it dispenses the drug to the patient. The specialty pharmacy then bills the patient's insurance company to recoup the cost of the drug and other associated service fees such as a dispensing fee and/or co-pay/co-insurance. Overwhelmingly, in order to bill the patient's insurance company, the specialty pharmacy must be in network with the patient's health plan. The health plan's pharmacy network is managed by its pharmacy benefit manager (PBM). Therefore, the health plan's PBM decides which pharmacy can and cannot be in its network for purposes of dispensing and then billing the health plan.

It is these contracts and relationships that NASP members urge the FTC to investigate as there is no negotiation that takes place between the PBM that owns its own specialty pharmacy and the independent specialty pharmacy seeking to join the network because the PBM, which as stated, manages the network also owns its own specialty pharmacy clearly providing a significant disincentive from letting any other specialty pharmacy in the network. By excluding other specialty pharmacies from its network, the PBM therefore drives more distribution revenue to its own subsidiary specialty pharmacy such that PBM is using its status as a PBM "gatekeeper" in one line of business to drive business to another line of business that it owns, which is a specialty pharmacy.

The PBM that owns its own specialty pharmacy is therefore incentivized to exclude other competitor specialty pharmacies. In doing so, the PBM that owns a specialty pharmacy achieves two important financial goals. First, to drive greater revenue and profit to its own specialty pharmacy given that the PBM owned specialty pharmacy is obviously in network with its parent corporate entity. Second, to create greater leverage in its purchasing power against manufacturers and wholesalers as a result of its greater influence in the network.

Since the PBM owned specialty pharmacy has such a large market presence it dictates many of the financial terms between itself and its commercial partners such as sellers and even its own health plan clients. In order to achieve this financial goal, the PBM uses its network contracting process to exclude other specialty pharmacies from its network.

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By shutting out independent specialty pharmacies from its network, the PBM is not only increasing its financial power but also reducing consumer and physician choice as to how to access the specialty drug. With fewer in network pharmacies comes reduced competition amongst and between specialty pharmacies in addition to fewer choices. Without this competition the incentives to compete on quality of care and patient outcomes are also dramatically reduced. Since the PBM owns the specialty pharmacy and there is little to no competition in its network, why would the PBM owned specialty pharmacy create quality of care programs and measure outcomes to attract physician prescriptions, patients or drug contracts from the manufacturers? Without the competition, the PBM owned specialty pharmacy receives all the prescriptions from the physicians without the need to innovate or improve patient services.

As the result of recent consolidation with a focus on vertical integration within the PBM and specialty pharmacy sectors, NASP believes that patient and provider choice of pharmacy has been reduced, quality of care has suffered, and we look forward to working with the FTC to provide further detail and specific examples.

Here are many examples of contract provisions and requirements offered by PBMs that also own a specialty pharmacy that NASP believes are used to exclude the independent specialty pharmacy from the network. Many, if not all of these provisions have nothing to do with the dispensing of a drug or servicing the patient and/or provider further evidencing the anti-competitive intent of the provision which is to exclude and not include.

NASP Examples:

- 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 URAC, the Joint Commission, CPPA, and/or ACHC. NASP supports third party accreditation[6] as a tool to drive competition based on uniformly applied measures, standards and processes. Recently, however, many PBMs that also own a specialty pharmacy are requiring accreditation by their own PBM as a condition for network participation. In addition to charging a fee for this accreditation, the accreditation includes a detailed audit of business processes, capturing photos and reviewing other proprietary and strategic documents all under the auspices of network credentialing.

[6] http://naspnet.org/wp-content/uploads/2017/02/NASP-Defintions-final-2.16.pdf

Most of this entire process is not relevant at all for the independent specialty pharmacies' ability to dispense drug and take care of patients. Rather, independent specialty pharmacies believe that it is an attempt to gather sensitive competitive business intelligence that will be used in their own specialty pharmacy. In other words, there is very little confidence in the fire wall that is supposed to exist between the two entities.

For example, recently a NASP member applied to be in network and after going through the credentialing process was notified that the specialty pharmacy did not meet the PBM's standards. This specialty pharmacy is dually credentialed in specialty pharmacy and has provided impeccable service to several IDN / health system clinics that require a very high service standard. From this denial, it is apparent that the PBMs are devising their own credentialing standards making current nonbiased third party accreditation less relevant.

- Providing contract terms that under reimburse drugs—As mentioned above, independent specialty pharmacies contract with PBMs to be in network. Since the PBM owned specialty pharmacy is also a purchaser of that same drug from the manufacturer/wholesaler it knows the purchase price. Because the PBM knows the purchase price and is incentivized to keep independent specialty pharmacies out of network, it often offers drug reimbursement rates below the purchase price of the independent specialty pharmacy. 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 obvious attempt 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 marketplace as detailed above.

- Due to class of trade definitions, specialty pharmacy, which is not a defined class of trade, are contracted in network as either a retail or mail order pharmacy, but is neither. Because the PBM also typically owns its own mail order pharmacy it never offers the independent specialty pharmacy a contract that allows for delivery of medications to patients via the mail in conjunction with fair and equitable reimbursement for the medications dispensed and the critical patient care support services provided which would be much more in line with the independent specialty pharmacy's business model. Rather, independent specialty pharmacies are contracted as a retail pharmacy and therefore has the constant threat of being removed from network hanging over its business because at any time the PBM can cancel the network agreement because the specialty pharmacy is typically in violation of its retail agreement. This threat obviously

does not exist for the 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 that has the downstream effect of improving the finances of the PBM owned specialty pharmacy.

- In some circumstances, the PBM will require a prior authorization from an in-network pharmacy but will waive the prior authorization if patient uses PBM owned specialty pharmacy. In addition, while the prescription is "under review" the PBM owned specialty pharmacy sometimes fills and dispenses the specialty drug thereby essentially stealing the prescription from the independent specialty pharmacy. This is further evidence of blurring of any fire wall between the PBM and their specialty pharmacy.

- During a contracting process, the PBM that also owns the specialty pharmacy often refuses to provide actual reimbursement rates by drug or the applicable rate schedules associated with the various PDP Sponsors further disadvantages the independent specialty pharmacy.

- NASP members have witnesses a circumstance where an erroneous patient notification was sent by a PBM that owns a specialty pharmacy indicating that a non-PBM owned independent specialty pharmacy can no longer service their specialty prescription needs because the specialty pharmacy is no longer in network when in fact the non-PBM owned specialty pharmacy is contracted to be in network. This obviously causes unnecessary stress, potential disruption in care and confusion for both patients and physicians. In some documented cases, a PBM in negotiation with a pharmacy to amend or re-contract with the pharmacy sent notifications out to the pharmacy's patients indicating the pharmacy is no longer contracted with the PBM, and asking the patient to find another network pharmacy to avoid care disruptions.

III. PBMs that Own a Specialty Pharmacy Routinely Use That Vertical Integration to Drive Unfair Business Practices and Engage in Anti-Competitive Behavior

NASP Examples:

- Patient Steering—PBMs requiring patients to use their own specialty pharmacy even though other in network pharmacies have same price and perhaps better patient services and outcomes.

- PBMs use their formulary power to require limited distribution drug access from manufacturers in return for positive formulary coverage—As discussed, manufacturers sell their drugs/biologics to either the specialty pharmacy or wholesaler. For certain small subset of drugs/biologics that either treat a small patient population and/or have special handling requirements, manufacturers typically limit the number of purchasers to those qualified entities that are best able to serve the patients who need these types of drugs. The PBM owned specialty pharmacy is as equally interested in being in network with the manufacturer as the independent specialty pharmacy because of the revenue generated from the transaction and any subsequent profit gained from this transaction. Because the PBM owned specialty pharmacy "has visibility" into the formulary process it will often use this relationship in its negotiations with the manufacturers to extract network access and sometimes with better terms than its competitor. For example, if a crowded therapeutic category exists and therefore there are numerous products available for treating a condition or diagnosis (i.e. plaque psoriasis) and in the absence of treatment guidelines which specify the sequencing of products, PBMs will use their specialty pharmacy's access to the specialty drugs or lack thereof as part of the formulary inclusion/coverage decision making process. In other words, the clinical nature of the drug is not considered.

- Requiring broad access to medications that are not relevant to patients being served—Many PBMs require in network pharmacies to stock a wide range of drugs. Given the unique patient populations that many specialty pharmacies serve, it is not necessary to stock a wide range of drugs as the specialty pharmacy does not serve a wide patient population. This is yet another term used by the PBM that also owns a specialty pharmacy to exclude because it does not require this of itself.

- Excessive professional insurance requirements to participate in network.

- As mentioned above there are many examples of PBMs using a patient's prescription, which is HIPAA protected information for its own financial gain that possibly violates HIPAA by using the patient information to market and solicit to their own pharmacy providers.

- The PBM owned specialty pharmacy programs their own system to reject a claim at the network pharmacy that it does not own. This then prompts the PBM to reach out to physician and redirect the prescription to their own pharmacy. This seems to NASP to be an unfair marketing practice.

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- PBM that owns a specialty pharmacy calls the independent specialty pharmacy stating there is an error in the information entered for a prescription and ask the pharmacist and the independent specialty pharmacy to reverse the prescription submission, correct it and resubmit the prescription. During the minute it takes for the prescription to be reversed and updated by the independent specialty pharmacy, the PBM owned specialty pharmacy will fill the prescription. If the independent specialty pharmacy asks the PBM owned specialty pharmacy to reverse the claim it will state that the prescription was processed and is in the shipping department and cannot be reversed. The independent specialty pharmacy has now lost the patient to the PBM owned specialty pharmacy purely because of the vertical integration. There are many types of variations of this behavior that leads to the PBM owned specialty pharmacy dispensing the drug as a direct result of the fact that the PBM, which is its parent company, received the initial prescription for adjudication.

IV. Conclusion

NASP greatly appreciates the opportunity to submit these comments and looks forward to continuing to work with the FTC to ensure that all patients have access and choices to critical specialty drugs. NASP believes that the FTC has the authority to intervene and act on behalf of patients to ensure that each patient navigates the healthcare system with many choices and that those entities from which they are to choose are competing with each other based on quality and outcomes. Please contact me at (703) 842-0122 if you have any questions regarding our comments. Thank you for your attention to this very important matter.

Sincerely,

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