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Federal Trade Commission
Office of the Secretary
Room H-113 (Annex X)
600 Pennsylvania Ave, NW
Washington, DC 20580

Re: Health Care Workshop, Project No. P13-1207

In response to the Federal Trade Commission ("FTC") and the Department of Justice ("DOJ") in workshop "Examining Health Care Competition," which was held on February 24-25, 2015, we write on behalf of the Independent Specialty Pharmacy Coalition ("ISPC") to provide overview comments, particularly concerning restricted network access by pharmacy benefit managers in the wake of major consolidation, and its impact on independent specialty pharmacies.

Health care competition and enforcement needs greater focus on specialty pharmacy services and the ability of independent specialty pharmacies to be able to effectively treat patients. Specialty pharmacy now comprises approximately 25 percent of the national drug spend,[1] and will equate to roughly 9 percent of the overall health care expenditure in the United States by 2020.[2] With recent consolidation in the pharmacy benefit manager ("PBM") market, combining two of the top four PBMs, the PBMs have been able to secure greater strangleholds on independent pharmacies increasing the usage of limited networks, limiting consumer choice, and reducing access to affordable prescription drugs.

Formed in 2010, the ISPC is a coalition made up of a number of leading specialty pharmacies across the country with the intent of providing independent specialty pharmacies with a voice in regulatory and legislative matters. We serve thousands of specialty patients who value the service, counseling, and assistance they receive from community specialty pharmacies.

The Nature of Specialty Pharmacy

Specialty pharmacies provide treatments for our nation's most vulnerable patient populations suffering from chronic, complex conditions such as hemophilia, Crohn's Disease,

[1] *The Growth of Specialty Pharmacy*, UNITEDHEALTH CENTER FOR HEALTH REFORM AND MODERNIZATION (2014), *available at* http://www.unitedhealthgroup.com/~/media/UHG/PDF/2014/UNH-The-Growth-Of-Specialty-Pharmacy.ashx.
[2] *Id.*

hepatitis C, infertility, HIV/AIDS, and many forms of cancer. The specialty treatment for these conditions are generally very expensive and often require special handling and control as well as complex administration, as is the case with injectables and infusions. Given the dynamic nature of many of these disease states, intensive and consistent monitoring is vital to effective patient care in this area.

Independent specialty pharmacies and federally funded hemophilia treatment centers provide a vital level of clinical pharmacy services to the hundreds of thousands of Americans that depend on specialty treatments. They are not mere drug dispensaries but instead play an active role in providing continuity of patient care to ensure that costs are minimized and health outcomes improve. They work with clinicians to set up treatment regimens, coordinate care, and determine the effectiveness of treatments. They educate patients on effective utilization, how to inject and administer medications, and how to detect adverse side effects. For treatments requiring infusion, many specialty pharmacies offer home infusion services or access to infusion centers. In many situations, specialty pharmacies serve as the link between doctors and patients in monitoring therapy, including side effects, medication combinations, and ineffective treatments. The services provided by specialty pharmacies support the most cost-effective use of these expensive treatments and help to keep these patients healthy and out of hospitals. Therefore, independent specialty pharmacies are inordinately valuable for protecting these patients' wellbeing and containing health care costs.

Restrictive Networks and the Effects on Specialty Pharmacies and Patients

Each of the largest PBMs, Express Scripts (ESI), CVS/Caremark and Catamaran RX, has acquired their own mail-order specialty pharmacies and through benefit plan designs often requires the exclusive use of their wholly-owned specialty pharmacies. This vertical-integration raises significant conflicts of interest. The role of a PBM is to secure the highest quality, lowest cost pharmaceutical benefits for their clients; yet, the financial interests associated with owning a specialty pharmacy establish strong incentives for PBMs to funnel business to its subsidiary specialty pharmacies to maximize the profits of their affiliates, which is what has occurred with each of the largest PBMs mentioned above. PBMs are no longer the honest brokers hired to secure the best deals on pharmaceutical goods and services, but rather, middlemen with perverse business incentives to drive customers and profit to their affiliated businesses.

Vertically-integrated PBMs push plan sponsors to network designs that heavily favor their affiliated specialty pharmacies by charging a penalty price for not complying with a closed network. The penalty involves charging plan sponsors more for pharmacy benefit designs that enable patients to choose a pharmacy other than the PBM's mail order pharmacy. The result of this penalty price is a *de facto* exclusive arrangement through which PBMs are able to exclude even the most efficient competitor. These restricted networks significantly limit competition in the specialty pharmacy market and, ultimately, threaten patient care and wellbeing.[3]

[3] The economic harm of such penalty price schemes is set forth in Einer Elhauge, *Tying, Bundled Discounts, and the Death of the Single Monopoly Profit Theory*, 123 HARV. L. REV. 397 (2009); *see also* David S. Sibley, Patrick Greenlee, & David Reitman, *An Antitrust Analysis of Bundled Loyalty Discounts*, INT'L J. OF INDUS. ORG., (2008) vol. 26, pp. 625-642.

Competition among specialty pharmacies is quite unique in the health care sector. Patients typically rely on physician referrals for specialty pharmacies as patients generally lack familiarity with specialty pharmacy services. Physicians are the best equipped market participant to direct patients to the appropriate pharmacy, because they possess knowledge of their patients' needs, an ability to evaluate proper specialty pharmacy care, and no perverse incentives. Accordingly, competition for physician referrals is an important and unique characteristic of the specialty market.

Recent consolidation in the PBM market has eroded away at this vital level of competition. The 2012 merger of Express Scripts and Medco, followed by the acquisition of SXC by Catamaran, and the recently announced acquisition of Catamaran by Optum Rx, leaves only three dominant PBMs in the market. While the Catamaran/Optum merger is still pending, the FTC has let the other consolidation in the market occur on the belief that there is sufficient competition among PBMs. However, as Commissioner Julie Brill has stated, the notion that PBM "competition 'is intense' is debatable."[4] Commissioner Brill further notes that "I continue to believe the PBM industry was then [during the 2012 ESI/Medco merger] – and remains today – highly concentrated…This market structure, combined with the 90 percent customer retention rate and significant installed bases enjoyed by the Big Three, all pointed – in my careful estimation – toward a market that, once the merger was consummated, would become a "duopoly with few efficiencies in a market with high entry barriers – something no court has ever approved."[5]

This continuing market consolidation will lead to coordination among the large PBMs.[6] The coordination has begun to and will continue to diminish competition for physician referrals as the dominant PBMs can simply compel businesses to utilize their exclusive network arrangements. Along with the loss of physician referral competition, patients will lose the value of physician expert opinion in selecting appropriate specialty pharmacy care. Moreover, patients will be forced away from the specialty providers they know, trust, and prefer, oftentimes resulting in increased overall healthcare costs due to problems with adherence and treatment administration. In fact, exclusive PBM networks can lead to disruptions in care for the vulnerable patients whose wellbeing depends on strict adherence and consistent monitoring.

Similar concerns over restricted networks exist specifically for service to Medicare Part D beneficiaries as well. As representatives of independent pharmacies, we have long supported increased access for beneficiaries. When Congress enacted Medicare Part D, the goal was to preserve patient access and choice by permitting any willing pharmacy to participate in a prescription drug plan ("PDP") network so long as it met the plan's conditions. Unfortunately, restricted Part D networks have become common place, particularly those run by PBMs that own their mail order pharmacy. As a result, PBMs have severely limited the choice Part D beneficiaries have in access to pharmacies. CMS recognizes this problem finding "that most PBMs own their mail order pharmacies, and we believe their business strategy is to move as

[4] Letter by FTC Commissioner Julie Brill to Larry Good, Executive Secretary of ERISA Advisory Board, U.S. Department of Labor (August 19, 2014).
[5] *Id.*, citing *FTC v. H.J. Heinz Co.*, 246 F.3d 708, 717 (D.C. Cir. 2001).
[6] *Id.* (noting that coordination between PBMs at the time of the ESI/Medco merger "was feasible and ongoing.").

much volume as possible to these related-party pharmacies to maximize profits from their ability to buy low and sell as high as the market will bear."[7]

Lastly, there is an increasing need for specialty pharmacists to manage the ever-growing costs in the specialty drug realm. By 2018, specialty drug costs are expected to surpass the total spent on all traditional drugs combined.[8] Prescription Drug Plan sponsors often place specialty drugs on a "non-preferred brand tier" which can cost payors and beneficiaries thousands of dollars a month in specialty drugs.[9] With rising usage and higher costs, it is essential for plans to utilize the services of community-based specialty pharmacists who focus on disease management techniques, waste management, and medication adherence which ensure that a beneficiary receives proper care while also lowering overall cost.

Conclusion

Specialty drugs are quickly becoming one of the fastest growing and costliest items in the health care arena. Independent specialty pharmacies play a vital role in treating patients with some of the most complex and chronic health conditions who are in need of specialty drugs. Competition for services and their existence is threatened by the ability of dominant PBMs to significantly restrict networks to include only their captive specialty pharmacies. With the recent wave of consolidation, which only seeks to further diminish the ability of independent specialty pharmacies to compete to provide the best health care to consumers, we recommend the FTC reexamine the PBM market post-Express Scripts/Medco merger with a focus on increased consolidation harming competition within the specialty pharmacy market.[10]

We appreciate the FTC and DOJ's consideration of the above comments and recommendation.

Sincerely,

David A. Balto

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[7] CMS-4159-P Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs; Proposed Rule at 1975.

[8] ARTEMETRX, SPECIALTY DRUG TREND ACROSS THE PHARMACY AND MEDICAL BENEFIT (2013), *available at* http://www.artemetrx.com/docs/ARTEMETRX_Specialty_Trend_Rpt.pdf.

[9] *See* Jack Hoadley et al., *Medicare Part D Prescription Drug Plans: The Marketplace in 2013 and Key Trends*, 2006-2013, KAISER FAMILY FOUNDATION (Dec. 11, 2013), *available at* http://kff.org/medicare/issue-brief/medicare-part-d-prescription-drug-plans-the-marketplace-in-2013-and-key-trends-2006-2013/.

[10] This recommendation is not new, but it is severely needed. Commissioner Brill has called for such reexamination of the PBM market a few times over the last couple of years – First, in her 2012 dissent statement to the ESI/Medco merger, and second, at a December 3, 2013 oversight hearing before the House Commerce Committee. This should become a priority for the FTC.