**Ken Buck's Questions for House Judiciary Antitrust Subcommittee**
**3.7.19**

**Questions for Fiona M. Scott Morton:**

I'm concerned that lack of fair competition to expensive biologic drugs, such as Johnson and Johnson's Remicade (used for Chron's Disease, Ulcerative Colitis, Rheumatoid Arthritis, Psoriasis), despite the approval of lower-cost biosimilars, will harm patients and ultimately discourage further investment in complex generics and biosimilars.

1. Do you think CMS should act to ensure generics and biosimilars are automatically placed on preferred insurance formulary tiers to ensure patient access to affordable medicines? Do you support recent proposals by HHS within the CY 2020 Medicare Part D Call Letter to require generic drugs be placed on generic insurance tiers and brand name drugs to be placed on brand tiers?

Remicade was approved by FDA in 1998. Despite loss of market exclusivity and the entry of a lower-cost biosimilar more than 2 years ago, Remicade has maintained more than 90% of the market for the drug. The premise behind generic and biosimilar market competition is that patients will benefit by accessing lower-cost medications. I'm concerned that brand companies are distorting this system and blocking patients' access to affordable drugs, including biosimilars.

2. In the recently released CY 2020 Medicare Part D Call Letter, HHS proposed to create a new "specialty drug insurance tier," reserved exclusively for specialty generic drugs or biosimilars that would reduce cost-sharing for seniors. Do you believe Medicare Part D should incentivize utilization of biosimilars, and would this approach ensure seniors receive the full benefit of lower-cost medicines?

**Question to the Panel on Biosimilar Market Competition:**

Background: When Congress passed the Biologics Price Competition and Innovation Act (BPCIA), it was intended to increase competition in the biologic market by creating a pathway for approval for interchangeable biologics and biosimilars. Unfortunately, while FDA has now approved 17 biosimilars, only 7 of them are on the market. The others remain tied up in patent disputes between the brand and biosimilar manufacturers. These patent disputes occur even when the brand's exclusivity period has long since expired.

Question: FDA has now approved 17 biosimilars, but most of them aren't on the market due to patent disputes. Why is this happening, even when the branded drug's market exclusivity has expired?

**Questions to the Panel on Consolidation:**

1. Hospitals have been eagerly using their purchasing power to acquire community cancer clinics, dramatically shifting cancer care into more expensive hospital settings over the past decade. A 2016 report indicated a 172% increase in the consolidation of community oncology practices into hospitals since 2008,[1] and 2018 numbers show an 11.3% increase in the number of community cancer clinic closings and an 8% increase in the number of consolidations into the hospital setting.[2]

[1] Community Oncology Alliance, Practice Impact Report, October 2016 (available at: https://www.communityoncology.org/2016-coa-practice-impact-report/)

[2] Community Oncology Alliance, Practice Impact Report, April 2018 (available at: https://www.communityoncology.org/wp-content/uploads/sites/20/2018/06/COA-Practice-Impact-Report-2018-FINAL.pdf)

In January 2018, a New England Journal of Medicine study concluded that the 340B program is associated with hospital-physician consolidation in hematology-oncology.[3] It is important to identify and study drivers like 340B to ensure that other Part B infusion drugs do not follow the same trend, thereby increasing patient costs and limiting access to community care even further. This is particularly a problem in rural areas that already face barriers to access.

- What impact does this consolidation of the cancer care system from community settings into hospitals have on costs to the health care system? On cancer patients and their individual cost burden? On taxpayers?

2. A 2015 study by Berkeley Research Group found that (disproportionate share hospitals - DSH) hospitals have been driving consolidation of oncology practices and on average more than doubled their oncology services. The result of this consolidation has led Part B reimbursement on oncology products to increase by 123% for 340B hospitals while non-340B hospitals had a 31% increase and physician groups suffered a 5% decrease.

- With no signs of a slowdown in program growth, will this site of care shift from lower-cost providers like community practices to higher-cost providers like 340B hospitals be sustainable in the long run? Do we know how much this consolidation is costing the system?

3. We have seen data documenting the consolidation of community outpatient settings into hospitals and how that is driving up healthcare costs generally, but this also impacts prescription drugs. In 2015, the GAO reported that per beneficiary Medicare Part B drug spending was substantially higher at 340B (DSH) hospitals ($144) than at non-340B hospitals ($60).[4]

- As companies' exposure under the program continues to rise, in some cases into the $3-4 billion, is it reasonable to expect that costs are shifting to other non-340B sites of care?
- The New England Journal of Medicine stated in 2018 that while, "the program is intended to expand resources for underserved populations but provides no incentives for hospitals to use financial gains to enhance care of low-income patients."[5] In Part B, beneficiaries must pay 20 percent of the cost of the benefit provided, but there is no requirement to pass along direct savings from the 340B discount. With reimbursement rates higher in the hospital, doesn't that increase patients out-of-pocket? Shouldn't we ensure patient co-pays are based on the prices hospitals pay to acquire drugs or at the very least not subject patients to increased out-of-pockets through this shift in site of care?
- Would it make sense to look at reforms to the 340B program in the context of drug pricing to address market distortions that may be shifting costs and increasing the financial burdens onto patients?

## Questions to the Panel on PBMs:

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[3] Desai S. McWilliams M. Consequences of the 340B Drug Pricing Program. N Engl J Med. 2018. Accessed: https://www.nejm.org/doi/pdf/10.1056/NEJMsa1706475

[4] Medicare Part B Drugs. Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals. June 2015. https://www.gao.gov/products/GAO-15-442

[5] Desai S. McWilliams M. Consequences of the 340B Drug Pricing Program. N Engl J Med. 2018. Accessed: https://www.nejm.org/doi/pdf/10.1056/NEJMsa1706475

Three Performance Benefit Mangers (PBMs) control 80% of the PBM market. In theory, this should give them leverage to negotiate lower drug prices. But my understanding is that PBM's profits are at least partially tied to the manufacturer's list price.

- Doesn't that actually create an incentive for PBMs to see prices increase?

One of the three PBMs, OptumRx, recently told drug companies they couldn't lower prices unless they gave almost two years notice and paid the PBM the same amount of money, despite the lower price. (https://www.beckershospitalreview.com/pharmacy/optumrx-sets-demands-for-drugmaker-price-reductions.html)

- Why would a drug manufacturer ever lower its price if a PBM is just going to take more of its profit?