Written Testimony on:

Bringing Transparency and Accountability to Pharmacy Benefit Managers

Unites States Senate

Committee on Commerce, Science & Transportation

Debra Patt, MD PhD MBA

Medical Oncologist

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I thank Committee Chair Cantwell, Ranking Member Cruz, and members of the committee for the opportunity to share my views on PBMs.

What follows is my written testimony with links to relevant and important references included. I highly recommend that the committee read these materials, starting with the expose on PBM tactics/behaviors.

As background, I am Dr. Debra Patt, an oncologist specializing in breast cancer in Austin, Texas. I serve in the leadership of Texas Oncology, a large independent community oncology practice that is part of The US Oncology Network, and I serve as Vice President of the Community Oncology Alliance.

PBM transparency and accountability is critical because patients being able to get their oral cancer drugs in a timely, effective, and sustainable way allows them to realize the benefits of modern cancer therapy. PBMs steering the filling of these pills to their specialty and mail order vertically integrated pharmacies all too often results in unnecessary delays, denials, and waste for cancer patients getting potentially life-saving drugs.

This is a remarkable time when instead of cancer treatment disrupting how patients live and work—or even being a death sentence—they can enjoy their life with their cancer and control it as a chronic disease, like hypertension or diabetes. Americans with cancer can work at their jobs, teach at their schools, pick up their kids from soccer practice, and eat dinner with their families.

Oral cancer drugs account for about 30 percent of cancer therapies and we anticipate this soon growing to 60 percent. The increasing use of these effective, but expensive specialty drugs, and their profit potential, has attracted the top PBMs, with the largest three controlling 80 percent of the prescription drug market and, adding the next three largest, the top six PBMs control 96 percent of the prescription drug market. This gives these PBMs, who are owned by or own the largest health insurers, substantial leverage in controlling what treatment patients get and how, when, and where they receive it.

PBMs frequently delay and detour appropriate and timely therapy for my patients. The delays and detours are difficult to anticipate and limit a doctors' ability to effectively control the cancer, and delays can lead to poorer disease control, morbidity, and mortality.

Doctors frequently modify treatment doses to optimize therapy and control toxicities, sometimes in as little as 1-2 weeks after starting treatment. When a PBM mail order pharmacy is only willing to fill 90-day supplies of cancer medications this can lead to extremely expensive waste or suboptimal dose modification.

As a breast cancer doctor, I will illustrate some PBM issues using the oral cancer drug abemaciclib (brand name Verzinio) as I write for this medication frequently for patients

with ER+ breast cancer. This drug is incredibly beneficial and improves survival in patients with advanced breast cancer but has some substantial toxicity with diarrhea that requires management and dose modification. The medication is also unique because it is helpful in treating brain metastasis, which many cancer therapies do not treat.

Tania is a 40-year-old woman with metastatic breast cancer that has now metastasized to her brain. When her cancer grew in October 2022, I recommended we use abemaciclib in addition to other medications on November 1, 2022 and explained to Tania that because we would have to go through her insurance company and PBM I was uncertain how quickly she might get the medication. I told her that the therapy has been published in peer reviewed literature and I was optimistic it was her best shot at continuing her quality of life and slowing her disease progression—especially in her brain. After the pills were denied, and I appealed, I was informed it could take six weeks to even have a peer review and they couldn't tell me when in the next six weeks I would be called to appeal the decision. While this seemed unreasonable, because it would allow Tania to feel well enough to continue to work and allow her to keep her hair, I was inclined to continue to try to get the medication for her. In the coming weeks as Tania was off treatment her disease worsened and she developed metastasis in the skin on the side of her trunk. I could see it growing and I told her we really couldn't wait any longer to see if her insurance would cover the abemaciclib, and we would have to do something different. In December, when I still had not been able to talk to a doctor to have her treatment approved, I started her on traditional chemotherapy in addition to a targeted therapy. Since December, Tania has stopped working. When I saw her in follow up last week we spoke about her two new brain metastasis we observed on her brain scans and how we would try to address those with additional radiation treatments.

We very commonly see how vertically integrated PBMs and their corporately affiliated specialty pharmacies delay appropriate therapy, especially when they demand that patients use their mail order pharmacies to get their cancer drugs and other specialty therapies. The Community Oncology Alliance (COA) has done a good job of characterizing these challenges and relating real-life patient stories, which I have attached to this testimony. When you have an advanced cancer, delaying initiation of treatment can contribute to morbidity or mortality.

Most often, with the PBM involved, we don't know when the patient will receive the medication, and after it is initiated, the cadence of refills is also a challenge. What the PBMs do is effectively "rip" quality medical treatment out of providers' hands and the site of care. Rather than help in care coordination they disjoint care. This leads to delays, denials, waste, and poor patient outcomes.

For example, when I see patients with advanced breast cancer and I prescribe abemaciclib, I am seeing these patients every two weeks to make sure that their toxicity of diarrhea is well managed and so I can dose reduce as necessary. Dose reduction is common and

important in cancer care as it can lead to improved tolerance of the medication and enhanced adherence. When patients receive oral cancer drugs at our office-based medically integrated pharmacy, we can see a patient, check labs, and made dose modifications prior to the refill. That does not happen when the drug is filled by a PBM vertically integrated specialty mail order pharmacy. Routine refilling usually happens from PBMs at the same dose, without real time dose modifications. This leads to wastage of a month's supply or the patient taking the incorrect dose that will make the therapy more toxic. For abemaciclib, that could result in well over $10,000 of waste per month.

I will note that when we are allowed to fill the prescription at the point-of-care in our clinic, our medically integrated pharmacy is subject to fees typically months after the medication is filled. These fees are referred to as direct and indirect renumeration (DIR Fees). These are fees that are supposed to be anchored to quality but are based on factors that are not indicators of quality in the cancer patients we treat. These DIR Fees have grown considerably over time, with DIR Fees in our practice comprising less than four percent of total cost seven years ago to more than 11 percent of cost today. This is an unexpected expense that we cannot anticipate or influence. These DIR fees are based on quality metrics that are not reflective of quality treatment in the patients I serve. For example, filling drugs to treat blood pressure and high cholesterol is not something I usually do in a cancer practice. And I will additionally note that these onerous DIR Fees are also assessed on independent pharmacies across the country, causing many to close and creating pharmacy "deserts" for patients.

I want to underscore, that due to the power of the top PBMs, the majority of oral cancer drugs are not filled at our medically integrated pharmacy but are steered by the PBMs to their corporate-affiliated specialty mail order pharmacies. PBMs tell you that this is a cost saving measure, but in reality it allows them to effectively control the practice of medicine.

We urgently need PBM transparency and accountability.

I thank Senator Cantwell for her leadership in shining the light of transparency on PBM practices and for working with Senator Grassley, and his leadership, on an issue that knows no political divide. The lives of our patients, and your constituents across the country, are very at stake. ***Action to stop PBM destructive behavior is needed more than ever.***

Additional abuses of PBMs, including but not limited to the following:

- "Fail first" step therapy requiring cancer patients to first fail on inferior cancer treatment or supportive care therapy before getting the most effective medication.
- Using prior authorizations to unduly delay and even deny cancer treatment.
- "Trolling" patients to steer them to PBM-owned or affiliated mail order pharmacies causing patient confusion and worry.

- Using rebates literally to extort price concessions from pharmaceutical manufacturers that do not get passed on to patients and to block using the least expensive drug like a biosimilar.
- Using "co-pay accumulators" to pocket co-pay assistance funding that should be going to reduce patients' deductibles.

Rather than elaborate on all the PBM abuses I see on a daily basis, I am including with this testimony materials that will help the committee better understand the abuses of PBMs, and how they have infiltrated other areas of medicine. However, so as not to make this document unmanageable in emailing, I have included links (below) hyperlinked to the source material. This research was aggregated with the assistance of the Community Oncology Alliance.

Thank you for the opportunity of testifying and submitting this written testimony for the record.

PBM Studies:

- PBM Dirty Tricks Comprehensive Exposé Report: https://communityoncology.org/featured/pbm-dirty-tricks-expose/
- PBM DIR Fees Investigative White Paper on Background, Cost Impact, and Legal Issues: https://communityoncology.org/wp-content/uploads/2017/01/COA_White_Paper_on_DIR-Final.pdf
- Report on PBM "Performance" Based DIR Fees: https://communityoncology.org/research-and-publications/studies-and-reports/performance-based-dir-fees-a-rigged-system-with-disparate-effect-on-specialty-pharmacies-medicare-part-d-beneficiaries-and-the-us-healthcare-system/

COA Comment Letters and Filings:

- Formal Comments to FTC on Harm of Pharmacy Benefit Manager Integration: https://communityoncology.org/research-and-publications/comment-letters/coa-formal-comments-to-ftc-on-harm-of-pharmacy-benefit-manager-integration/
- Letter to DHA on Tricare PBM concerns: https://communityoncology.org/research-and-publications/comment-letters/letter-to-defense-health-agency-on-tricare-pbm-concerns/
- Amicus Brief on PBM Contract Pharmacy Takeover of 340B Program in AstraZeneca dispute: https://communityoncology.org/research-and-publications/comment-letters/coa-amicus-brief-in-340b-contract-pharmacy-dispute-22-1676-az/

PBM Horror Stories Series: https://communityoncology.org/category/research-and-publications/pbm-horror-stories/

1. https://communityoncology.org/research-and-publications/studies-and-reports/the-real-life-patient-impact-of-pbms-volume-i/
2. https://communityoncology.org/research-and-publications/studies-and-reports/the-real-life-patient-impact-of-pbms-volume-ii/
3. https://communityoncology.org/research-and-publications/studies-and-reports/the-real-life-patient-impact-of-pbms-volume-iii-2/
4. https://communityoncology.org/research-and-publications/studies-and-reports/pharmacy-benefit-manager-horror-stories-part-iv-2/
5. https://communityoncology.org/research-and-publications/pharmacy-benefit-manager-horror-stories-part-v/