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Coalition of State Rheumatology Organizations

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The Coalition of State Rheumatology Organizations (CSRO) is comprised of over 40 state and regional professional rheumatology societies whose mission is to advocate for excellence in the field of rheumatology, ensuring access to the highest quality of care for the management of rheumatologic and musculoskeletal disease. Our coalition serves the practicing rheumatologist. CSRO thanks the Federal Trade Commission (FTC) for the opportunity to provide feedback on its request for information related to the pharmacy benefit manager (PBM) industry.

As practicing rheumatologists, we experience firsthand the consequences that high out-of-pocket costs have on medication adherence and, thus, our patients' quality of life. The drugs available to treat rheumatoid arthritis and other autoimmune diseases are often heavily rebated, yet still prohibitively expensive for patients. This tells us that the current system is broken. It is our understanding that the FTC may begin a comprehensive study of the PBM industry. As explained in greater detail below, the contracts between PBMs and drug companies are the cause of the formulary and utilization management issues faced by our patients, so we urge the FTC to include a thorough examination of the interactions between these two industries in any eventual study.

Foundational question: Who is the consumer?

The incredible levels of horizontal and vertical consolidation in the PBM industry are well-known, but there has been little evaluation of whether this consolidation has changed the identity of the PBM's "customer." In the view of physicians, our healthcare system should consider the patient the primary consumer. Although healthcare involves a "payer" that is usually distinct from the patient, patients are being asked to pay ever-increasing monthly premiums, deductibles, and out-of-pocket costs for needed services and items. Yet our current drug supply chain treats patients as an afterthought.

Before the vertical consolidation within the big three PBMs, payers were usually considered a PBM's primary customer. Now that these PBMs own or are owned by insurance companies, however, this can no longer be true, because a healthy

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contractual relationship requires that the parties be potentially adverse, or at least have some potentially adverse interests. In addition, the vertical consolidation is

not just limited to insurers and PBMs: the big three PBMs now own *entirely* consolidated supply chains, in some cases all the way down to the physician's office, which is the point of origin of any prescription. Finally, the increasing amounts of price concessions from pharmaceutical companies call into further question which entity is the customer. In 2017, the Securities and Exchange Commission (SEC) raised precisely this question after Express Scripts – now part of Cigna – included in filings the revenues that it received from drug companies as "customer receivables." As the SEC pointed out, this classification was strange because drug companies were not a customer of the PBM. However, pharma receivables were around a third of all of its customer receivables.[1]

The FTC and other regulatory agencies may need to tailor the regulatory approach to the varying ownership scenarios among the parties in our drug supply chain. **A single guiding principle that should apply regardless of ownership status is that the *patient* must be centered as the primary consumer**. After all, nearly 80% of patients are at the mercy of three entities that control *what* medication patients can take (through formulary construction), *when* they can take these medications (through utilization management), *where* they can purchase them (through pharmacy networks), and *how much* they must pay for them (through cost-sharing). Currently, all of these decision points (what, when, where, and how) are leveraged to maximize PBM revenues rather than to serve the best interest of the patient.

List prices must be high to maximize PBM revenues

One of the few drug companies that makes public its rebating information reports that, over the last six years, it has experienced an almost 17% *decline* in net prices. In 2021, a year of high consumer inflation, net prices across the company's medicines declined by 2.8%.[2] Other companies have reported similar observations. Yet very few – if any – patients tell us that their out-of-pocket costs for prescription drugs have gone down in the last five years. This begs the question: where is the money going?

[1] "The Feds just asked a huge healthcare company who their real clients are and the answer is totally unsatisfying" by Linette Lopez, *Business Insider* (Dec. 7, 2017): https://www.businessinsider.com/sec-looks-into-express-scripts-rebates-from-pharmaceutical-firms-2017-12.

[2] Janssen 2021 transparency report: https://2021jtr.prod.cmc.jnj-secondary.psdops.com/_document/the-2021-janssen-u-s-transparency-report?id=00000180-0108-dccf-a981-a52ec8300000.

Researchers have found that the current rebating system – which takes credit for declining net prices – has driven list prices upward.[3] The list price is a starting point for negotiations between the drug company and the PBM; thus, it must leave headroom for the significant price concessions that the PBM will extract in return for favorable formulary placement. If these price concessions were fully passed through to the patient, this system could be positive for the consumer. In reality, however, list prices seem to be fictional for everyone *except* the patient, whose cost-sharing is often based on that price point.

Patients are steered towards drugs that maximize PBM revenues

The formularies themselves can help identify what goals they serve. If the goal is to reduce costs for patients and payers, then many of the formularies are counterintuitive. If the goal is to maximize PBM revenues from price concessions, the formularies are perfectly sensible. For example, the brand version of the prostate cancer drug abiraterone is $10,000, while its generic is $450. Yet several PBMs only cover the brand version.[4] In fact, a review of formularies found that Aetna and Humana had the generic on Tier 4/Specialty Tier, while UnitedHealthcare did not seem to cover the generic at all, or perhaps only at a certain dosage.[5] Freezing a cheap generic off formulary to the benefit of the expensive brand makes sense if the goal of the formulary is to maximize rebate potential for the PBM. For the patients who pay coinsurances based on list prices and for the employers who pay for coverage, however, this formulary construction is nonsensical. This type of situation is especially disastrous for patients with high deductibles, who will have to shoulder their entire deductible with one prescription fill.

Until recently, stories of these types of formulary designs were anecdotal, but researchers are increasingly documenting these situations. For example, the Office of the Inspector General examined biosimilar coverage in Medicare Part D and confirmed that formularies are not designed to prioritize biosimilar uptake: in 2019, 38% of formularies that covered an epoetin alfa reference product did not cover a biosimilar and 32% that covered the pegfilgrastim reference product did not cover a biosimilar. In other words, about a third of formularies in Part D exclude these biosimilars from coverage.

Moreover, the OIG confirmed that utilization management and tiering play a role here too, finding that more than 97% of Part D formularies placed all covered biosimilar and reference

[3] "The Association Between Drug Rebates and List Prices" by Neeraj Sood, Ph.D, et al., Leonard D. Schaeffer, University of Southern California, Leonard D. Schaeffer Center for Health Policy & Economics (Feb. 11 2020): https://healthpolicy.usc.edu/research/the-association-between-drug-rebates-and-list-prices/.

[4] "When the $10K brand name drug is more affordable than its $450 generic: How PBMs control the system" by Zachary Brennan, Endpoints News (Feb. 18, 2022): https://endpts.com/when-the-10k-brand-name-drug-is-more-affordable-than-its-450-generic-how-pbms-control-the-system/.

[5] *Id.*

product filgrastims and pegfilgrastims on the same tiers and more than 60% placed all epoetin alfa biosimilars and reference products on the same tiers. The formularies did not leverage utilization management to encourage uptake of the biosimilar products. The OIG closed by predicting that for Humira and Enbrel, which account for billions of dollars in Part D spending, plans may have "even more incentives to limit formulary coverage or to employ utilization management tools to potentially discourage the use of biosimilars for these biologics. This is because drug manufacturers pay substantial rebates to Part D plans, potentially encouraging Part D plans to cover the manufacturers' reference products instead of the corresponding biosimilars, or to give the reference products preferential treatment."[6]

Congress created the approval pathway for biosimilars in 2010, but without reform of the current rebating system, patients will not experience the savings that we all expected these products to create.

Specialty drugs are categorized and tiered to maximize PBM revenues

As the example of abiraterone illustrates, a generic may end up on the "specialty" tier, which is generally where we expect high-cost, single-source brand name drugs to be. This oddity points to another key enabler of this broken system: the lack of any uniformly applied industry standards or definitions in contracts or formulary design. The resulting definitional gaming makes it nearly impossible to gain a comprehensive picture of the revenues flowing into this industry.

One year's rebate is next year's administrative fee. A PBM's lower cost is a patient's higher price. A drug company is not a customer even though its payments are customer receivables. Even terms clearly defined by the Food and Drug Administration are not safe from this definitional wizardry: a generic may become a brand in one contract, but remain a generic in another. The lack of standardization of key terms – enabled by the lack of transparency – leaves regulators and lawmakers in a never-ending game of definitional whack-a-mole, legislating and regulating after inconstant definitions and recharacterizations.

This also applies to how medications are clinically categorized: etanercept, which is commonly used in rheumatoid arthritis, is classified in three different ways by three different PBMs in Part D formularies. This is especially challenging in rheumatology because the products we use have different mechanisms of action. A JAK inhibitor is different from a TNF inhibitor, but often the formularies will treat these medications as interchangeable and only allow coverage of one, or limit coverage of one at the expense of the other. Treating these medications as the same means

[6] "Medicare Part D and Beneficiaries Could Realize Significant Spending Reductions With Increased Biosimilar Use" Suzanne Murrin, Deputy Inspector General for Evaluations and Inspections, Office of Inspector General, U.S. Department of Health and Human Services (March 2022): https://oig.hhs.gov/oei/reports/OEI-05-20-00480.pdf.

that one can be leveraged against the other in price concession negotiations, but it leaves patients without access to the full array of treatment options.

Pharmacy choice is restricted to maximize PBM revenues

Many rheumatologists that have the capacity for in-office drug administration "buy and bill" their medications, but PBMs have begun to force patients who need in-office administration into their own pharmacies via so-called "white bagging" policies. Patients drafted into this model must serve as their own care coordinators, practice administrators, and financiers, since they must coordinate with the specialty pharmacy, work through utilization management requirements, authorize medication dispensing to the administration site, and – at the risk of the specialty pharmacy not shipping the drug – pay the full cost-sharing up front. If the medication cannot be used as planned (because, for example, the patient experienced weight gain requiring a dosage change), then the medication must be discarded, without a refund to the patient. This process is wasteful, administratively cumbersome, and can result in significant delays in treatment.

Insulin

Insulin is often cited as a "poster child" for our broken drug pricing system. Even accounting for innovation in release timing and delivery mechanisms, it is difficult to justify how one of the oldest medications has experienced such drastic price hikes in the last five years. Here too, all indicators point to the existence of perverse incentives driving up prices for patients. A comparison of 2017 insulin spending by Medicare Part D compared to that year's insulin sales by the drug companies found over $2 billion in "missing" sales, meaning sales that were reported in Part D but did not appear in the companies' balance sheets.

Although the research examined costs charged under Medicare Parts B and D for various medications, the Part D insulin data was, in one of the researcher's words, "the strangest data we saw[.]"[7] He further observed that: "It is interesting that the drug with the lowest Medicare Part D sales had more than five times the sales volume outside of Medicare Part D. In contrast, Sanofi, with the biggest spread between what it books as revenue in its annual report and what it credits in Medicare sales seems to get the largest Medicare Part D sales volume."[8]

While it is difficult to point to a single reason for this odd observation, these "missing sales" must go *somewhere*. However, our current drug supply chain lacks the transparency that would allow policymakers or researchers to determine where that is. At a minimum, data such as this shows that there is a disconnect for policymakers such as the FTC to further examine. As the researcher

[7] "Insulin prices and pharmacy benefit manager rebates: pin the tail on the patient" Duane Schulthess, *Stat First Opinion* (March 19, 2020): https://www.statnews.com/2020/03/19/insulin-prices-pbm-rebates/.
[8] *Id.*

concluded: "While our data aren't proof that pharmacy benefit managers are gobbling up some, if not all, of this insulin margin, it is possible, even probable. It is also possible to imagine a scenario in which PBMs play the drug companies off one another, offering the largest insulin sales volume to those providing the biggest margins in the PBMs' direction. […] So where is the $1.3 billion in missing sales for Sanofi's Lantus and $606 million in missing sales for Novo Nordisk's Novolog? It might be sitting in PBM bank accounts. One thing for certain is that it isn't coming back to consumers as discounts and it isn't going to the pharmaceutical companies that make the products."[9]

Practicing physicians have also observed that although there are now two interchangeable biosimilars for Lantus, only the higher-priced one is available on the formularies of many PBMs. The price concessions may reduce the net cost so that it is the lower-cost option for the PBM. However, the patient is often still paying on the higher list price. If this dynamic continues to occur, the cost-saving potential of biosimilars will accrue mostly to the PBMs rather than patients. We are hopeful that a comprehensive FTC study could shine light on where "missing sales" are absorbed and to what extent the price concessions are driving formulary placement of more expensive options.

Transparency would jeopardize this business model

The industry has fought any efforts towards transparency tooth and nail, because any visibility into the revenue streams would hamper the ability to engage in the various conduct described above. The industry demands that policymakers accept its claim that price concessions are passed through to patients because it says so.

Several states have brought litigation against their PBMs on the issue of spread pricing, which is a practice enabled by the lack of transparency. Unfortunately, litigation seems to be the only way in which payers can determine whether a PBM has met its contractual pass-through obligations. Soon, even litigation may not even provide a method to gain access to price concession information, as the Big Three have created entities they refer to as rebate aggregators, some of which are organized offshore. As a recent article described, "PBMs purport to relay 100% of rebates PBMs received back to the Plan, but in reality, PBM-owned rebate aggregators are known to retain a significant amount of manufacturer rebates."[10]

Solutions

[9] *Id.*

[10] "Cautionary tale: Plan sponsors losing manufacturer rebate dollars to PBMs through rebate aggregators" by Jonathan E. Levitt and Dae Y. Lee, *BenefitsPRO Expert Opinion* (April 15, 2021): https://www.benefitspro.com/2021/04/15/cautionary-tale-plan-sponsors-losing-manufacturer-rebate-dollars-to-pbms-through-rebate-aggregators/?slreturn=20211015144426.

While the problem is complex, the solutions need not be. Formularies should be constructed on efficacy, safety, and lowest list price, which removes kickbacks from the picture and creates a race to the bottom of pricing, as opposed to our present system which fosters a race to the top.[11]

If that is impossible at this time, at the very least, we could implement a system in which:

- All middlemen would be paid a fixed fee based on market value of their services.
- Patients would pay coinsurance on the post-kickback cost of the drug.
- Stable patients' medications would continue to be covered regardless of changes in health plan formularies

These reforms would bring us closer to a system that centers the *patient* as the ultimate consumer to be served. **We urge the FTC to conduct a full, comprehensive investigation of the PBM industry so that Congress and other stakeholders can move forward with informed, thorough policy reforms**.

Sincerely,

Madelaine Feldman, MD, FACR
President
Coalition of State Rheumatology Organizations

[11] "Formulary Construction in America: Perfectly Legal and Perfectly Wrong" by Madelaine Feldman, MD, FACR, *Healio* (Nov. 19, 2019): https://www.healio.com/news/rheumatology/20191113/formulary-construction-in-america-perfectly-legal-and-perfectly-wrong.