

STATEMENT OF MADELAINE FELDMAN, MD, FACR
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Forum: “Reviewing the Role of Pharmacy Benefit Managers in Pharmaceutical Markets”

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Thank you to Ranking Member Comer for hosting this forum and the invitation to participate, and to all of the Members in attendance. My name is Madelaine Feldman. I have been a rheumatologist for thirty years and I practice full-time in New Orleans. I am also the current President of the Coalition of State Rheumatology Organizations (CSRO).

The best place to begin any discussion about drug pricing and patient access is with a few examples that illustrate how counterintuitive and harmful our current system is:

1. Three rheumatoid arthritis medications share the same mechanism of action. One of the three is priced at roughly half of the other two, and the difference is significant: approximately \$30,000 per year versus \$65,000-\$70,000. Yet only the two expensive drugs are able to get on formulary. This means that the cheapest option has only 3% market share; the remainder of this market is dominated by the two expensive products.¹
2. A prostate cancer patient can only access the brand name drug that costs \$10,000, because the \$350 generic is not on their employer’s health plan formulary.
3. At least one pharmacy benefit manager is working to prevent access to a test that can predict a patient’s response to the drugs in a highly rebated drug class.
4. Despite insulin having become the poster child for our country’s drug pricing issue, currently only the highest priced interchangeable insulin can gain formulary access; other, cheaper biosimilar insulins are kept off formulary.
5. Recently, a large health insurer sent patients with rheumatic diseases a \$500 cash card offer and essentially forced them to switch drugs to the one preferred by the insurer, even though the patients were stable on their present drug.²

If we could design a drug pricing system from scratch today, I doubt that any Member of Congress – Democrat or Republican – would design the dystopian one we are living with now. That begs the question: how did we get here?

¹ “Formulary Exclusions Favor Rinvoq Use and Increase Costs” *American Rheumatology Network* (May 15, 2020). Available: <https://americanrheum.com/news/formulary-exclusions-favor-rinvoq-use-and-increase-costs/>.

² “Cigna Dangles \$500 to Persuade Patients to Switch Psoriasis Drugs” by Allison Inserro, *American Journal of Managed Care* (March 26, 2021). Available: <https://www.ajmc.com/view/express-scripts-dangles-500-to-persuade-patients-to-switch-psoriasis-drugs>.

Specialty medications can be miraculous, but they come at a cost.

In my practice, we treat patients with a variety of rheumatologic and immunologic conditions, including rheumatoid arthritis (RA). The treatment for RA has changed dramatically in the last three decades. When I graduated from medical school, all we could do for our patients was to provide symptomatic relief. Now, we have a range of medications that attack the disease itself and that can slow down or even stop joint damage. This is significant, because it means that RA does not inevitably lead to disability and a life of pain management. If their RA is well-managed, patients can live long and physically active lives.

Of course, if everything was rosy and our healthcare system was working wonderfully, the Committee would not be hosting this panel today. The out-of-pocket costs for these miraculous RA medications – as well as medications for many other serious, chronic illnesses – have risen to levels where many patients simply can no longer afford them, and that is true even for biosimilars. Clearly, something is not working the way Congress intended. That something begins with the formulary.

Formularies: pay to play

At its most basic, a formulary is a list of medications covered by a patient's health insurance plan. To construct these formularies, many plans contract with pharmacy benefit managers (PBMs). The PBMs negotiate with drug companies for rebates, discounts, and other price concessions. In exchange, the drug companies receive favorable formulary placement.

Placement on the first tier of a formulary is a coveted status because it leads to greater market share for that manufacturer. If that manufacturer's payments to the PBM are the highest, then the PBM will use its utilization management tools such as step therapy and non-medical switching to drive patients towards that medication. Formularies can be switched as frequently as every six months, to keep up with the latest contract negotiations between PBMs and drug companies. The payments from drug companies to PBMs are enormous and do not only consist of rebates: they include a myriad of fees, often based on a percentage of the list price, just like rebates. While I am not an attorney, it baffles me that these payments are legal; they are kickbacks by any reasonable definition of that word.

High drug prices are not a mere byproduct of this system; they are at the heart of its design, since a drug's list price must be high so as to offer "headroom" for these discounts, rebates, and fees to the PBM. This creates a broken market in which competition actually *raises* prices. In this way, our drug pricing system is more akin to selling a house than building a house:



All of this might be acceptable if the patient could gain access to the lower net prices, but a significant body of research has found that a patient’s coinsurances are often based on the list prices, *before* any of these discounts.³ This leaves patients with the worst end of the bargain on both sides: not only are they subjected to aggressive utilization management, they are also denied the benefit of cost-sharing reductions for the medications subject to said utilization management.

The “savings” PBMs deliver are revenues for themselves.

Once you grasp this system, you will begin to notice the careful wording by PBMs when they talk about the “savings” they create. If a PBM can achieve 50% of “savings” off a medication with a list price of \$8,000/month, that might lead them to prefer that medication over an equivalent that has a list price of \$4,000/month, because that 50% of “savings” accrues to the PBM. However, if the patients’ 20% coinsurances are assessed against the list price, then how do the patients benefit from the “savings”?

Furthermore, giving one pharmaceutical manufacturer preferred status year after year will of course result in that manufacturer's market share dwarfing everyone else's. The PBMs make lots of profit off of that drug company, but must create formularies to keep that company happy. This can result in the creation of a so-called “rebate wall,” in which the preferred manufacturer controls the formulary for an entire disease state and/or bundles different drugs together in the contract so as to essentially block other drugs from gaining preferred status.⁴

The discussion around “savings” reveals the underlying distortion of this broken market:

³ See, e.g., “New Analysis Shows Out-of-Pocket Spending Based on List Price” by Thomas Sullivan, *Policy & Medicine* (May 4, 2018). Available: <https://www.policymed.com/2017/05/new-analysis-shows-out-of-pocket-spending-based-on-list-price.html>.

⁴ “Drug ‘rebate walls’ should be dismantled by the FTC’s antitrust arm” by David Balto, *STAT First Opinion* (Dec. 4, 2018). Available: <https://www.statnews.com/2018/12/04/ftc-dismantle-drug-rebate-walls/>.

in our current system, the benefits of market competition accrue to the PBM, rather than the patient. Indeed, if the PBM is the consumer, this market is working splendidly: they continue to book record profits. However, if our goal is to center the *patient* as the primary consumer, then significant reform is needed.

PBMs threaten premium increases to avoid reform.

PBMs often argue that they use their negotiated “savings” to keep monthly insurance premiums low. Given the opacity of the revenue streams, this is impossible to verify but, if it is true, then we currently have a health insurance system in which the sick subsidize the healthy. Patients with serious chronic illnesses who are in need of expensive medications provide revenue that is used to slightly reduce premiums for all consumers (regardless of health status) covered by a health plan. This is the very opposite of the concept of insurance.

Moreover, this argument is disingenuous. In November 2017, the Centers for Medicare and Medicaid Services (CMS) published a request for information (RFI) related to a requirement for insurers in Medicare Part D to include at least a minimum percentage of manufacturer rebates and all pharmacy price concessions in a drug’s negotiated price at the point of sale.⁵ In the RFI, CMS plainly stated that, “In recent years, only a handful of plans have passed through a small share of price concessions to beneficiaries at the point of sale.” CMS modeled the financial impact of requiring various levels of pass-through of manufacturer rebates: 33%, 66%, 90%, and 100%. At the 33% level, beneficiaries would save \$19.6 billion dollars in costs over ten years. With a 100% pass-through, beneficiaries would save \$56.9 billion overall over ten years. While a pass-through policy would cause moderate premium increases, these increases were more than offset by the reductions in cost-sharing at every modeled percentage level.

The lack of industry transparency creates definitional whack-a-mole.

Now that health plan clients, employers, and lawmakers are focused on rebate reform, PBMs have begun to reclassify these revenue streams into various fees, so that, short of full transparency, policymakers will be chasing ever-changing redefinitions and reclassifications. Often, various fees are based on a percentage of the list price as well, which creates the same distortions. Most recently, PBMs have turned to rebate aggregators, which they sometimes refer to as group purchasing organizations or simply as contracting entities. All of the three major PBMs now have aggregators, some of which are organized offshore. These aggregators serve as yet another layer of obfuscation and may shift price concessions outside of the reach of legislative

⁵ Proposed rule, “Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program” (Federal Register, Nov. 28, 2017). Available: <https://www.federalregister.gov/documents/2017/11/28/2017-25068/medicare-program-contract-year-2019-policy-and-technical-changes-to-the-medicare-advantage-medicare>.

or regulatory reform.⁶ The complexity of this system is no accident, because complexity serves as a foil to avoid reform.

Solutions

While the problem is complex, the solutions need not be. In 2019, I described this solution in an article entitled *Formulary Construction in America: 'Perfectly Legal' and 'Perfectly Wrong'*: 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.⁷ 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. Thank you again for inviting me to participate in this important discussion.

⁶ "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). Available: <https://www.benefitspro.com/2021/04/15/cautionary-tale-plan-sponsors-losing-manufacturer-rebate-dollars-to-pbms-through-rebate-aggregators/?slreturn=20211015144426>.

⁷ Available: <https://www.healio.com/news/rheumatology/20191113/formulary-construction-in-america-perfectly-legal-and-perfectly-wrong>.