TESTIMONY OF MADELAINE FELDMAN, M.D.

ALLIANCE OF SPECIALTY MEDICINE

PRESIDENT, COALITION OF STATE RHEUMATOLOGY ORGANIZATIONS

COMMITTEE ON ENERGY AND COMMERCE

SUBCOMMITTEE ON HEALTH

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HEARING ON

"IMPROVING DRUG PRICING TRANSPARENCY AND LOWERING PRICES FOR AMERICAN CONSUMERS"

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Chairwoman Eshoo, Ranking Member Burgess, and distinguished Members of the Subcommittee, thank you for inviting me to testify on behalf of the Alliance of Specialty Medicine. My name is Madelaine Feldman. I have been a rheumatologist for thirty years and I practice full-time in New Orleans. I am the current President of the Coalition of State Rheumatology Organizations, which is a member of the Alliance of Specialty Medicine ("Alliance"). The Alliance is a coalition of national medical societies representing more than 100,000 specialty physicians from fifteen national specialty and subspecialty societies. We are a nonpartisan group dedicated to the development of sound federal health policy that fosters patient access to the highest quality care.

Drug Pricing

The treatment of rheumatoid arthritis (RA) has changed dramatically since I graduated from medical school in the eighties: we have evolved from being able to provide only symptomatic relief to the discovery of therapies that actually impact disease activity and slow down or even halt joint damage. The difference this has made to RA patients is nothing short of miraculous. Not that long ago, an RA diagnosis would lead to inevitable disability. That is no longer true. With appropriate disease management, people with RA can lead long and physically active lives.

In the last decade, however, the out-of-pocket cost for these treatments has risen to the point where many patients can no longer afford them. Even products that have been on the market for over a decade continue to rise in price each year, all while patients are being asked to shoulder ever-increasing deductibles and coinsurances. This has a direct impact on patient care: I have seen far too many patients ration doses or forego a prescription due to cost.

This Subcommittee has the difficult job of having to balance protection of innovation for future patients with current patients' need for relief from high costs. I hope you will find it helpful to hear my feedback as a practicing physician on some of the policies under consideration by the Subcommittee, as you work to strike this balance.

Reporting on Pharmaceutical and Device Samples[1]

The Physician Payments Sunshine Act ("Sunshine Act") was enacted as part of the Affordable Care Act, with the purpose of increasing transparency of relationships between manufacturers and the prescribing community. Section 3 of the Prescription Drug STAR Act (H.R. 2113) would broaden the scope of the Sunshine Act to include the total quantity and value of pharmaceutical and device samples in manufacturers' reporting.

[1] H.R. 2113 ("Prescription Drug STAR Act"), Section 3: Requirement for Manufacturers of Certain Drugs, Devices, Biologicals, and Medical Supplies to Report on Product Samples Provided to Certain Health Care Providers.

Samples in Rheumatology

In rheumatology, we do not receive samples of infused products. We receive samples of self-injectables or small molecule pills. The choice of treatment is not determined by what samples the office has because we receive samples of all specialty medications. In our specialty and many others, the out-of-pocket cost of the available products can be incredibly high: in some Medicare Advantage plans, patients may pay a 30% coinsurance. Since some of these products have list prices in the thousands of dollars, this puts treatment out of reach for many patients.

Even those who can afford these out-of-pocket costs are subject to aggressive utilization management by insurers and their pharmacy benefit managers (PBMs). Patients may wait weeks or even months before getting final approval and actually obtaining the medication. Prior authorizations have gone so far that they are sometimes required before a neurosurgeon can treat a gunshot wound to the head. To someone outside of the medical profession, this may sound absurd. For those of us who practice at the intersection of expensive drugs and complex, chronic disease, it is sadly unsurprising. Yet, similar to patients in need of high-level trauma care, in the case of a progressive, irreversible disease like rheumatoid arthritis, patients do not have the luxury of time. In these cases, when time is of the essence, we can offer samples of the proper medicine to the patient and teach them how to use it, all at no cost to the patient or the insurer while waiting for approval and delivery of the needed medication. Before even trying to get approval for specialty medicines for which there are no lower cost alternatives, all of the less expensive medicines have been tried and failed. Access to these samples make the difference between a patient beginning the timely treatment necessary to save their joints, or not.

Another equally important aspect of having in-office samples, particularly of expensive drugs, is that it offers the ability to check for side effects and tolerability before the patient or the payer incur significant costs. Access to samples enables us to evaluate the product's efficacy and tolerability in a way that is financially risk-free to the patient.

Physicians derive no financial benefit from samples. In fact, samples require staff resources to receive, store, and manage inventory.

MedPAC Recommended Limited Publication of Data

Data disclosed via the Open Payments program has helped shed light on the relationships between manufacturers and the prescribing community. And while MedPAC has been cited as recommending reporting on samples, MedPAC never recommended gathering this information and publishing it on a public website. In its June 2017 report, MedPAC recommended that "the Secretary should make information reported by manufacturers on free drug samples available to oversight agencies, researchers, payers, and health plans." MedPAC recommended that Congress authorize and require the Secretary to make this information available to these entities *under data use agreements*: any entity requesting access to this data would have to sign confidentiality and data use agreements. In its discussion of samples, MedPAC noted that "samples clearly offer benefits for many patients."[2]

The provisions in H.R. 2113, however, would go much farther than the MedPAC recommendation, by publishing the information publicly online, for any member of the public to characterize as they see fit. I fear that this will have a chilling effect on manufacturers' willingness to provide these samples. There is little value in this approach other than enabling the creation of

[2] MedPAC Report to the Congress: "Medicare and the Health Care Delivery System" (June 2017), Chapter 6, "Payments from drug and device manufacturers to physicians and teaching hospitals in 2015".

shame campaigns against physicians and manufacturers by Twitter experts, bloggers, and the like and, as a result, potentially reducing the availability of samples. I hope that the information provided above illustrate why that would be detrimental to patients.

Physicians in no way profit from having these samples in their offices and the false implication that they do, by publishing the cost of the samples, is harmful to the doctor-patient relationship and undermines patients' trust in their physicians. We urge the Congress to more closely follow MedPAC's recommendations to accomplish the important goals of H.R. 2113 without the bill's unintended consequences for patients.

Disclosure of Rebates[3]

Section 5 of H.R. 2113 would require publication of generic dispensing rates and price concessions by class of drug. Like many other stakeholders, the Alliance has noted in the past that the current rebating system creates perverse incentives that are not serving patients well. Most notably from the perspective of our patients, there is data to suggest that beneficiaries are not currently benefiting from price concessions in the form of reduced cost-sharing, as their coinsurances are based on list prices. Additionally, as I described earlier in my testimony, our member physicians report ever-increasing and aggressive utilization management tactics by PBMs that are interfering with the practice of medicine.

Further, as physicians, we wonder why formularies change constantly when the clinical value of the various products stays the same. In rheumatology, this is particularly pronounced. I have patients who are stable on a biologic treatment who have received letters from PBMs urging them to switch to a completely different medication, often another biologic, because it may be a

[3] H.R. 2113 ("Prescription Drug STAR Act"), Section 5: Public Disclosure of Drug Discounts.

less costly alternative. But the letters fail to note that such a switch would not always be less costly for the *patient,* nor is it good clinical practice or standard of care to switch a stable rheumatoid arthritis patient for non-medical reasons. This just happened to a long-time patient of mine, who is stable on a medicine with a unique mechanism of action: his PBM sent him a letter urging him to switch to a medication with a totally different mechanism of action, even though there is no clinical reason to do so. These letters are usually the PBM attempting to drive the patient to the product that provides a bigger price concession to the PBM. Sometimes, that product will actually have a *higher* list price.

It would be beneficial to disclose the financial transactions that play a role in formulary design because then we can begin to understand to what extent financial considerations are trumping clinical ones. This includes not only the formulary rebates but all of the price concessions, including those kept by the PBMs such as administration and price protection fees. Since price concessions are the basis for formulary design, the resultant utilization management requirements do not appear to be clinically driven. Rational utilization management would be based on safety, efficacy, and lowest list price. In light of these concerns, we support disclosure of rebates and other price concessions made to PBMs by manufacturers.

Drug Pricing Transparency[4]

Section 2 of H.R. 2113 would require drug manufacturers to submit justifications for price increases over a certain percentage or launch prices over a certain threshold amount. We believe in transparency in pricing across the board. If manufacturers must justify their prices, however,

[4] H.R. 2113 ("Prescription Drug STAR Act"), Section 2: Drug Manufacturer Price Transparency.

they should be allowed to include information related to the price concessions in their contracts with PBMs, even if that information is otherwise confidential or proprietary.

Out-of-Pocket Cap in Medicare Part D

The Part D benefit design did not contemplate the prescription drug market as it is today. In rheumatology, we are in a unique position in that the drugs we prescribe are covered by Parts B and D, depending on the administration of the product. For Medicare beneficiaries, Part B is much more preferable because many beneficiaries have some type of supplemental coverage, which is not the case in Part D. Additionally, Part B is free of middlemen, resulting in an open formulary structure with annual spending growth rates increasing at a slower pace than those of Part D drugs.

When an RA patient ages into Medicare and is stable on a drug covered by Part D, they often can no longer afford the Part D drug and must either switch to a Part B medication or hope they qualify for a foundation to pay for their medication. This happens because, while they previously had the benefit of copay assistance programs, this type of assistance is prohibited in Medicare. Thus, the patient suddenly has to pay a full 25% coinsurance on the list price of a product that used to cost them a more manageable out-of-pocket amount. Once they reach the catastrophic cap, the patient still owes 5% of these expensive products – and, given the high list prices, even that is often too much for the average Medicare beneficiary. This economically driven "forced" switch can result in loss of control of the disease which ultimately can lead to higher medical costs in the long run. If for some reason the patient cannot take a part B medication, they may lose all access to any medication that works for them, leading again to increased costs to the patient and the system.

Some reform of cost-sharing in Part D is desperately needed. This is especially critical for those suffering from chronic, complex illnesses, living on a fixed income, who resort to rationing their medications to pay for other living expenses.

Conclusion

The Alliance of Specialty Medicine is encouraged by the Congress' bipartisan attention to and action on drug pricing. While we believe some policies under consideration may need changes to avoid unintended consequences, we are supportive of increased transparency in the drug supply chain. Thank you for your consideration of our viewpoints.