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Answers to Questions for the Record
Subcommittee on Health
House Committee on Energy and Commerce
Health Care Spending in the United States: Unsustainable for Patients, Employers, and Taxpayers

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The Honorable Robert Latta

In 2023, over 8 Humira biosimilars launched in the US with expectations of producing significant cost savings for patients and the healthcare system, Medicare alone estimated that $2 billion could have been saved if access to and uptake for these biosimilars is robust. Today, all 8 of these combined have less than 5% update in Medicare Part D. Additionally, there are only a limited number of biosimilars covered. A 2022 ERISA Industry survey found that employers are concerned about costs and rebates and prefer all biosimilars to be included on formularies. There must be coverage of biosimilars on formularies—as they are approved, including mid-year—in preferred positions without restrictions and make them accessible to patients and providers. Products simply being listed on a formulary is not enough to ensure patient access or affordability. What do you believe is stifling competition?

What can Congress do to ensure greater access to lower cost biosimilars for Medicare Part D patients?

The long-run success of biosimilar markets requires both that biosimilars introduce price competition and that they gain non-trivial market share. In the short run, consumers benefit even if biosimilars induce reference biologics to lower prices, but gain little market share. In the long, however, there is little reason to believe biosimilar manufacturers will continue investing in future product development if they do not capture meaningful market share.

Evidence suggests that biosimilars are making significant progress on both fronts in the physician-administered market.[1] While there are many fewer case studies among pharmacy-dispensed biologics, early evidence from Humira is more concerning. I agree that rebating practices likely contribute to slow biosimilar uptake in some markets. I believe these concerns are most acute in markets where drugs manage chronic conditions. In these cases, the manufacturer of the original biologic can threaten to pull rebates to an insurer if they give a biosimilar preferential access over their originator product (for clarity, concern about rebates in this setting stems from the fact that they provide a *mechanism* through which an originator drug maker can immediately increase the price of a product). This is extremely powerful in these markets because drug manufacturers can be confident that health care providers are very reluctant to switch existing, well-managed patients from a biologic to a biosimilar.

I think there are two ways to increase access to biosimilars in these kinds of markets. First, policymakers can work to make it more likely that providers are willing to switch a patient from a biologic to a biosimilar. We now have significant evidence from clinical trials and real-world evaluations that suggest such switches can be done safely (both across biologics and biosimilars, as well as within different biosimilars).[2] For example, biosimilars could all be deemed

[1] E.g., see IQVIA. "Biosimilars in the United States 2023-2027. Competition, Savings, and Sustainability." January 2023.

[2] E.g., see de Oliveira Ascef, B., Almeida, M. O., de Medeiros-Ribeiro, A. C., de Oliveira Andrade, D. C., de Oliveira Junior, H. A., & de Soárez, P. C. (2023). Impact of switching between reference biologics and biosimilars of tumour necrosis factor inhibitors for rheumatoid arthritis: a systematic review and network meta-analysis. *Scientific Reports*, *13*(1), 13699; Allocati, E., Godman, B., Gobbi, M., Garattini, S., & Banzi, R. (2022). Switching among biosimilars: a review of clinical evidence. *Frontiers in Pharmacology*, *13*, 917814; Cohen, H. P., Hachaichi, S.,

interchangeable. Policies like these would reduce the ability of biologic makers to leverage existing patients to impede biosimilar take up.

Second, Congress could give biosimilars a leg up by giving them preference on formularies in some markets (most likely Medicare). I am uncertain for how effective this type of policy would be because it may only change incentives for a modest set of patients. For example, Medicare represents a modest portion of the market for many drugs and many patients receive low-income subsidies that reduce their exposure to cost sharing. That said, I understand the goal and think it is worth considering further.

Improving uptake of biosimilars—particularly in markets for chronic diseases—is an important policy question and I would be very happy to discuss this further with your office.

The Honorable Earl "Buddy" Carter

A recent claims analysis has demonstrated common hospital outpatient department (HOPD) procedure prices were substantially higher — in some cases, five times more expensive — than when performed in an ambulatory surgery center (ASC) or office setting. HOPD prices have grown rapidly, with a 27% average increase, compared to 11% for ASCs and 2% for physician offices. What do these increased payments mean for patients, the federal government and taxpayers?

If patients are receiving similar quality care in more expensive settings—notably HOPDs instead of ASCs or physicians' offices—patients, the federal government, and taxpayers all face higher costs for little benefit. Patients are very likely to owe a higher amount in cost sharing because of this and ultimately bear the burden of higher insurance premiums. The federal government directly pays more when this occurs in public programs like Medicare and indirectly pays if higher commercial health costs reduce taxable earnings. Taxpayers ultimately bear the burden of these increased federal costs.

In general, policy should establish incentives for care to be delivered in the lowest cost setting in cases where quality will not be adversely affected. Within the Medicare program, this would include site neutral payments for services that can be safely delivered in ASCs and physicians' offices.

The Honorable John Joyce

Ever-thinning margins increase pressure for independent physicians to consolidate with hospitals. Dr. Ippolito, could a policy that advances site neutral payments, and reinvests

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Bodenmueller, W., Kvien, T. K., Danese, S., & Blauvelt, A. (2022). Switching from one biosimilar to another biosimilar of the same reference biologic: a systematic review of studies. *BioDrugs*, *36*(5), 625-637.

savings into the physician fee schedule, lead to less hospital-physician consolidation in health care?

Yes, this policy would reduce incentives for physicians to consolidate with hospitals. Under the current payment policy, a physicians' office which merged with a hospital would be able to bill higher amounts for the same services. Both the hospital and physician are likely to earn more money after merging. Under site neutral payments, hospital outpatient departments would no longer be paid more for services that can be safely delivered in a physicians' office, eliminating this source of consolidation incentives. If some of the savings were spent on increasing the physician fee schedule, the incentive to integrate with a hospital may be reduced further. This would be true if the increased fee schedule improved financial viability of independent practices.

The Honorable Rick Allen

179 million employees receive health insurance from their employers. Employers pay about 75 percent of employee's health care premiums as part of employee benefits and spend more on health insurance than any other employee benefit.

How does this impact employers in offering employee benefits, as well as overall business operations?

High commercial health costs affect employers and employees in a host of ways. Perhaps most notably, if employers allocate an increasing amount of money towards their health insurance contributions, they have less money to allocate to wages or other forms of compensation. In this way, employees ultimately pay for the full cost of their employer-sponsored insurance plan—a result that has been confirmed in economic research.[3] Part of these higher costs are also borne by employees through higher out-of-pocket spending. For some firms, high health care costs may also affect their willingness or ability to offer health insurance to their employees (perhaps most likely among smaller employers). All told, health costs have an important impact on the benefits and wages offered to employees, making them a first-order concern to many businesses.

The Honorable Mariannette Miller-Meeks

You have written recently about shortcomings in the No Surprises Act and have stated that "there would be advantages to eliminating the IDR process and replacing it with an explicit payment standard or a requirement that facility-based clinicians contract with the same insurance plans as the facility." Who do you believe should be responsible for determining the "explicit payment standard," and would there be reason to believe that requiring

[3] E.g., Arnold, D., & Whaley, C. (2020). Who Pays for Health Care Costs. *The Effects of Health Care Prices on Wages*; Kolstad, J. T., & Kowalski, A. E. (2016). Mandate-based health reform and the labor market: Evidence from the Massachusetts reform. *Journal of health economics*, *47*, 81-106; Gruber, J. (1994). The incidence of mandated maternity benefits. *The American economic review*, 622-641.

facility-based clinicians to contract with the same insurance plans as the facility would cause more burden for the physician?

While the No Surprises Act has successfully shielded many patients from surprise medical bills, the Independent Dispute Resolution (IDR) process used to adjudicate disputes between insurers and providers has faced significant challenges.[4] A large volume of IDR cases has triggered very high administrative costs and delays for providers and insurers alike. In addition, IDR decisions have varied widely, creating uncertainty. Early data also suggests the process is likely to raise costs for consumers.[5]

As I have previously argued, some of these features are intrinsic to the IDR process, even in a situation where implementation was relatively smooth (i.e., without the ongoing legal challenges the current system has). I think there are substantive arguments in favor of using a payment standard or a contract regulation approach.[6] If Congress established a payment standard, it would be up to Congress to determine the level of those payments. While I recognize the challenge in choosing that level, the current system does not avoid these tradeoffs (i.e., it requires that arbitrators effectively make a similar decision).

I am not aware of a reason that a policy requiring "network matching" between hospitals and hospital-based providers would increase burden for physicians. Evidence suggests that the vast majority of hospitals effectively have alignment in network participation between these groups, suggesting it is relatively feasible.[7] It is also worth noting that part of my concern about the current system is that it generates significant administrative hassles and payment delays for providers. That said, I would be very interested to learn more about specific concerns facing providers in such a scenario.

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[4] For a discussion see Ippolito, B., Adler, L., & Fiedler, M. (2024). Assessing early experience with arbitration under the No Surprises Act.

[5] Hoadley, J. and Lucia, K. (2024). Report Shows Dispute Resolution Process in No Surprises Act Favors Providers

[6] For a fuller discussion of these arguments see, for example, Adler, L., Fiedler, M., & Ippolito, B. (2019). Network matching: an attractive solution to surprise billing. *Health Affairs Forefront* or Ippolito, B., Adler, L., & Fiedler, M. (2024). Assessing early experience with arbitration under the No Surprises Act.

[7] Cooper, Z., Scott Morton, F., & Shekita, N. (2020). Surprise! Out-of-network billing for emergency care in the United States. Journal of Political Economy, 128(9), 3626-3677.