This past week, the House Ways and Means Committee held another installment in an ongoing series of important Congressional hearings examining the issue of drug pricing. While Congress has maintained an intense and continued focus on the issue of drug prices, there are an increasing number of examples of members of Congress on both sides of the aisle, and members of the Administration, working on various aspects of the drug pricing issue, sometimes in a bipartisan manner.

This alert summarizes the recent House Ways and Means hearing, then reviews most of the relevant bills that have been recently introduced on drug pricing.

This past week’s House Ways and Means hearing, more so than prior hearings this year on the topic, seemed to reflect the recent trend regarding an increasingly visible, bipartisan agreement on several common policy themes. A number of members of the committee talked about the goal of making access to affordable medications and therapies a reality for more of the US population.
The panel of witnesses included a young patient with multiple, severe chronic health conditions who continues to face out-of-pocket costs that are unaffordable, despite having "outstanding employer-sponsored health insurance coverage"; a professor of pharmaceutical patent law; a PhD expert who heads a think tank-type policy organization that examines the challenges faced by US healthcare consumers, and the market impact of those challenges; a representative expert speaking to the issue of drug pricing as it impacts the senior citizen population; and, lastly, a PhD fellow with expertise in healthcare and retirement policy.

The House Ways and Means hearing was noteworthy in that it revealed a number of common themes, summarized below, some of which are already being reflected in pieces of bipartisan legislation that have been introduced this Congress.

- **Current reimbursement framework within Medicare may still not be working within the construct of today's healthcare market in the way lawmakers envisioned, relative to lowering healthcare pricing/costs.** A number of Republicans and Democrats on the committee seemed to agree with commentary and policy suggestions proposed by a few of the expert witnesses that (a) the current risk structure in place for Part D must be addressed and restructured and (b) the current "incentives" in place for pharmaceutical entities in Medicare are under-performing and, in some respects, having adverse impacts counter to what the incentives were likely intended to achieve within the program. Some members noted that Medicare is the largest purchaser in the US of pharmaceutical products and, therefore, provides one of the ways policymakers could effect change that will ricochet into the private health insurance market.

- **An "informed" healthcare market is just one aspect of what should be a multi-faceted drug price reduction effort, and there are pointed actions that could be taken to further support these efforts.** There was some agreement on this assertion by economic experts on the witness panel. A few notable, specific points were emphasized. First, there was receptivity among Democrats, as well as some Republicans, to the idea of a multi-pronged approach that would include addressing the "patent thicket" to better incentivize production of drugs and therapies that may require substantially longer clinical trial periods that otherwise have proved too much of a cost-risk relative to the shorter patent life — for example, early-stage cancer therapies, where more risk is present in the substantially longer clinical trial period required. Next, multiple witnesses raised the question as to how FDA administers exclusivities, at a time when more currently-existing therapies are able to gain renewed exclusivity by making some change to the originally patented compound. Lastly, there was discussion that Congress and the committees of jurisdiction should perhaps focus more on policies that would address pricing restrictions on new, novel therapies that are introduced to the marketplace with high price tags.

- **Members on both sides of the aisle asked what impact, if any, the witnesses felt the new requirement to display drug list prices in direct-to-consumer advertising may have in driving more value-based decision-making in consumer choices.** There was agreement among many members and witnesses that the additional requirement to display list prices in advertisements doesn't actually inform the consumer in any way about the actual cost of producing the medication, relative to what they end up paying at the pharmacy counter. More specifically, witnesses said the displayed drug cost does not adequately inform the consumer; the cost, they said, should be compared relative to the beneficiary consumer's specific insurance coverage, which itself varies from beneficiary to beneficiary, as does the out-of-pocket cost. Furthermore, additional factors of co-pays/out-of-pocket costs, compared against premium costs, and middleman negotiators, could lead to a completely uninformed healthcare market and, subsequently, more confusion for the beneficiary consumer.

- **There were assertions that the use of an International Pricing Index (IPI) to link US pharmaceutical pricing to the pricing for the same products in other foreign jurisdictions might maximize effective understanding of the existing international price differential.** Most witnesses supported the introduction of an IPI aiming to better inform American consumers and the market about pricing differentials between the US and other countries. It was argued that this type of information would help mitigate drug price increases and, over time, help better align global drug pricing. However, while the expert witnesses on the panel generally agreed that introduction of an IPI would help American consumers understand US market pricing relative to other countries, they also cautioned that the Congress and American consumers should not view this as an "apples-to-apples" comparison in light of the policy differential in modalities of healthcare service delivery and access, as well as the very different ways in which financing is structured in other countries relative to the US. While a number of committee members on both sides of the aisle seemed positively receptive to this commentary, it was clear they are still weighing the role and impact of making an IPI-type comparison a reality.

The overarching takeaway from this installment in the drug pricing debate is that there is increasing bipartisan
support for exploring ways in which the federal government can leverage its own involvement in our nation’s healthcare delivery system to assist in driving down drug prices. However, there is still significant disagreement about the policy changes that should be pursued.

The pressures will continue to increase on Congress to insert itself into this issue, and we expect a number of additional hearings and debate about specific legislation in the near future.

WEEK IN REVIEW: Summary of relevant drug pricing legislation introduced since January 29, 2019

1. Medicare Buy-In and Health Care Stabilization Act: On February 13, a group of House and Senate Democrats announced plans to introduce bicameral companion legislation to allow those aged 50-64 to buy into Medicare coverage. It would also authorize HHS to negotiate volume discounts on prescription drugs. In the House, Democratic Representatives Brian Higgins (NY-26), John Larson (CT-01), Joe Courtney (CT-02) and Peter Welch (VT-AL) took the lead in announcing the initiative, with at least 14 original co-sponsors lined up (all Democrats) before the legislation has even been formally introduced. In the Senate Chamber, Senators Debbie Stabenow (D-MI) and Tammy Baldwin (D-WI) will sponsor and introduce mirror legislation.

2. Stopping the Pharmaceutical Industry from Keeping Drugs Expensive (SPIKE) Act (S. 474): Introduced by Democrat Senator Ron Wyden, this legislation would amend the Social Security Act to henceforth require drug manufacturers to publicly justify unnecessary price increases. Introduced February 13 with 8 original co-sponsors (all Democrats).

3. Reducing Existing Costs Associated with Pharmaceuticals for Seniors Act of 2019, or the RxCAP Act of 2019 (S. 475): Legislation also introduced by Democrat Senator Ron Wyden would amend the Social Security Act to prevent catastrophic out-of-pocket spending on prescription drugs for seniors and individuals with disabilities. Introduced February 13, with 5 original co-sponsors (all Democrats).

4. Creating Transparency to Have Drug Rebates Unlocked (C-THRU) Act of 2019 (S. 476): This legislation, also introduced by Senator Wyden, would amend the Social Security Act to provide greater transparency of discounts provided by drug manufacturers. Introduced February 13, with 3 original co-sponsors (all Democrats).

5. Stop Price Gouging Act (S. 378/H.R. 1093): This bicameral legislation would amend the Internal Revenue Code of 1986 to establish an excise tax on certain prescription drugs which have been subject to a price spike, and for other purposes. Introduced February 7, with 4 original co-sponsors (all Democrats).

6. Medicare Negotiation and Competitive Licensing Act (S. 377/H.R. 1046): This bicameral legislation would amend the Social Security Act to require the Secretary of Health and Human Services to negotiate prices of prescription drugs furnished under Part D of the Medicare program. Introduced Senate side on February 7 by Senator Sherrod Brown (D-OH) with 2 original co-sponsors (both Democrats). Introduced House side on February 7 by Representative Lloyd Doggett (D-TX), with 110 original member cosponsors.

7. Forcing Limits on Abusive and Tumultuous (FLAT) Prices Act of 2019 (S. 366): This legislation, introduced by Senator Richard Durbin (D-IL) proposes shortening monopoly periods for prescription drugs that are the subjects of sudden price hikes. Introduced February 6, with 5 original co-sponsors (all Democrats).

8. [Bill title not yet posted] (S. 334/H.R. 990): Bicameral companion legislation introduced in the Senate by Senator Thom Tillis (R-NC) and in the House by Representative Bill Flores (R-TX) proposes amending the Federal Food, Drug, and Cosmetic Act and the Securities Exchange Act of 1934 to prevent the inter parties review process for challenging patents from diminishing competition in the pharmaceutical industry and with respect to drug innovation, and for other purposes. Introduced February 6, with no original co-sponsors in the Senate or House.

9. Creating and Restoring Equal Access To Equivalent Samples (CREATES) Act: Legislation introduced by Senator Patrick Leahy (D-VT) would promote competition in the market for drugs and biological products by facilitating the timely entry of lower-cost generic and biosimilar versions of those drugs and biological products. Introduced February 5, with 27 original co-sponsors (13 Democrats, 13 Republicans, 1 Independent).

10. Patient Affordability, Value and Efficiency (PAVE) Act: In slightly different fashion than the majority of legislation introduced in Congress, a bipartisan duo, Senators Bill Cassidy (R-LA) and Mark Warner (D-VA), very recently released a discussion draft on which they are currently requesting comments and feedback to ensure highly technical changes enabling value-based arrangements are thoroughly.
vetted and that important oversight protections are preserved. This legislative draft would facilitate new and innovative payment models for pharmaceuticals and other medical services so that patients have better access to treatment, the healthcare market is more efficient, and drug prices are more affordable.

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