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Drug Pricing

AMGN to PBMs: Game, Set, Match

THE TAKEAWAY

In our view, Amgen's (AMGN) announcement to lower the list price of Repatha® by 60 percent is as much driven by the politics of the drug pricing debate as it is by Amgen's need to price the drug competitively. While Amgen's need to lower Repatha's list price has been an inevitability since Regeneron (REGN)/Sanofi (SNY) lowered the price of Praluent in May and cost Repatha placement on Express Scripts' (ESRX) largest formulary, Amgen's approach of lowering the list price puts PBMs on the defensive and essentially dares PBMs to not add them to their formularies. If PBMs stick with Praluent's rebate, it is an argument for the Trump Administration to move forward with its regulation of rebates. If PBMs shift to the lower-list price Repatha, we may see other manufacturers follow suit and the pressure to regulate rebates will subside. Investors should view this as a bullish move: Amgen is both undermining PBM's negotiating power by offering one list price to all purchasers, and placing the PBM industry on its heels in determining their next move. This strengthens our conviction that the pharmaceutical industry will ultimately win their war against the supply chain, and PBMs and wholesalers will need to begin to shift to non-rebate, alternative revenue sources they referenced on their 2Q earnings calls.

In our view, Amgen's (**AMGN**) announcement to lower the list price of biologic PCSK9 inhibitor Repatha® (evolocumab) by 60 percent is as much driven by the politics of the drug pricing debate as it is by the need to price the drug competitively. Amgen's move is an opening salvo in the latest battle in PhRMA's war against the drug supply chain as contributors to high drug prices.

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- The need for Amgen to price Repatha® more competitively has been an inevitability since Regeneron (REGN)/Sanofi (SNY) lowered the price of competitor Praluent in May and displaced Repatha® on Express Scripts' (ESRX) largest formulary. Amgen referenced their pricing challenges with Repatha in their 2Q earnings report: "In an effort to reduce access burdens, we have taken a number of actions to reduce the net price of Repatha® through offering greater discounts and rebates to payers. Despite the recent net price reductions, payers may continue to impose access burdens, change formulary coverage for Repatha®, seek further discounts or rebates or take other actions that could reduce our sales of Repatha®."
- But Amgen's approach to price competition--lowering list price rather than offering a higher rebate--is
 a strategy they may not have otherwise employed if it weren't for the Trump Administration's focus on
 popping the gross-to-net bubble and reducing list prices and out of pock costs. Amgen's press release
 emphasizes their decision to lower list price is in order to lower out-of-pocket costs for patients, especially
 Medicare beneficiaries, "75 percent" of whom never fill a prescription for "a PCSK9 inhibitor...due to high outof-pocket costs."
- In reducing the list price for Repatha®, Amgen risks losing formulary access as they phase out the drug's higher list price discounted via rebate. (The company has indicated they will maintain both their new list price and previous higher price through approximately the end of 2020 to allow time to transition thier current contracts.) Pharmacy benefit managers (PBMs) may continue to prefer Praluent because of its attractive rebate.
- But in our view, PBMs will face enormous political pressure to include Repatha® at its new lower list price on their formularies. Choosing instead to prefer higher priced, rebated Praluent would signal to the Trump Administration that PBMs are unwilling to shift away from the rebate model to a lower list price, and may need to be forced via regulation. The Administration "stick" is a draft regulation currently pending at the White House that may significantly change the current safe harbor protections for drug rebates under the federal anti-kickback statute.
- In lowering the list price for Repatha®, Amgen has created an opportunity for PBMs to show regulators that they do not need federal regulation to shift current pricing practices away from the rebate model. If PBMs take the opportunity, it would support the PBM industry's argument that changes to rebates regulation are unnecessary. If PBMs do not prefer Repatha® with the lower list price, it would validate the Administration's policy focus and rulemaking on rebates.
- In announcing this price decrease two weeks before midterm elections, Amgen appears to be currying favor
 with the Trump Administration by supporting the goals of its Drug Pricing Blueprint. But the timing also gives
 Regeneron/Sanofi time to consider lowering the Praluent list price ahead of January.
- In the coming months, we will be watching for the following: (1) whether Amgen's strategy works and leads PBMs to prefer Repatha® at its new lower list price; (2) whether other manufacturers, including Regeneron/Sanofi, follow suit; and (3) whether the Administration declares victory on lowering list prices and out-of-pocket costs without having to reform rebate regulation.
- Investors should view this as a very bullish move for pharmaceutical manufacturers, and note that in offering a lower list price without a rebate, Amgen threatens the benefit of PBMs' market power in negotiating lower prices. Amgen is not offering a lower price to larger PBMs who can drive more share-they appear to be offering the same list price to all purchasers. In our view, this should help pharmaceutical manufacturers, but not hurt PBMs and wholesalers significantly. Manufacturers would get to retain all of the revenue of a lower list price, and PBMs and wholesalers will need to shift revenue models as rebates for

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- some drugs are phased out. On their 2Q earnings calls, PBMs and wholesalers attested that they could shift to alternative revenue models (see our August 20 report on industry commentary on rebates regulation).
- Investors should also view this as a bullish political move. Amgen's announcement strengthens our view that pharma will ultimately win the war against PBM rebates and the role of the supply chain in pricing. It also supports our view that regulators may not need to make major changes to policy in order to change the drug pricing landscape. In this example, it seems that the Administration's bully pulpit may be working to effect industry-driven change. The question is whether PBMs will cooperate.

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COMPANIES MENTIONED IN THIS REPORT

Amgen Inc (AMGN), Express Scripts Holding Co (ESRX), Regeneron Pharmaceuticals Inc (REGN), Sanofi Shs Sponsored American Deposit Receipt Repr 1/2 Sh (SNY)

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