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How The Failure Of US PBM Reform Shaped Sanofi's Decision To Exit Diabetes R&D

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By Cathy Kelly

AND HOW IN CONTRAST, NOVO NORDISK is launching its oral GLP-1 agonist for diabetes at a price that may set up 'business as usual' tensions with pharmacy benefit managers and payers.

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Sanofi CEO Paul Hudson's recently-announced decision to discontinue research and development and new launches in the diabetes/cardiovascular arena offers a window into how US lawmakers' failure to reform pharmacy benefit management is playing out for at least one company.

Hudson recently joined Sanofi from Novartis and his plan to break with the past and walk away from diabetes research was announced as part of his new vision for the company during a presentation to investors . *(Also see "As Sanofi Exits Diabetes R&D, Meaning Of 'Diabetes R&D' Blurs" - Pink Sheet, 17 Dec, 2019.)*

The decision was driven by the expectation that formidable reimbursement challenges in the US diabetes market will continue. "You'll see us abandon … the 'me too' and 'me too late' development track and commercial track in markets with high rebate walls and five, six, seven years of negative" trend, he announced.

"We're not going to bother with them," because the resources needed to overcome the reimbursement challenges would be better spent by the company on opportunities elsewhere, Hudson explained. "We need to recognize that … the US is an attractive market" if "you have a transformative medicine."

As part of its new strategy, Sanofi will not commercialize its in-development GLP-1 agonist for diabetes, efpeglenatide, and has relinquished US rights to the

PCSK9 inhibitor, Praluent (alirocumab), which it has co-marketed with Regeneron Pharmaceuticals Inc.

> **"If we underestimate [PBMs'] ability to control, whether the price or the volume, then we miss a big opportunity in the market" elsewhere. "I think we're battle scarred enough not to go there again." – Sanofi's Hudson**

Hudson highlighted the role of pharmacy benefit managers in controlling pricing and access in the diabetes/cardiovascular category, noting the failure of an Administration effort to change the system in 2019 will allow those practices to continue.

The Administration's push for rebate reform was spearheaded by Health and Human Services Secretary Alex Azar, himself a veteran of rebate wars with PBMs during his tenure at Eli Lilly & Co. But concerns held by others in the Administration that the reform would drive dramatic increases in Medicare costs ultimately led to the

White House deciding to abandon the rule in July. *(Also see "Pharma's Big Defeat: US Rebate Proposal Hits The End Of The Road" - Pink Sheet, 11 Jul, 2019.)*

"We tried as an industry to rein in these middlemen … to get some transparency, to blow that up, to stop these perversities of why you don't get access" for certain drugs, Hudson noted.

But now, "we have to be really thoughtful about how we go into the new world and what we're expecting as a result of it, because if we underestimate [PBMs'] ability to control, whether the price or the volume, then we miss a big opportunity in the market" elsewhere. I think we're battle scarred enough not to go there again."

Novo Counting On Oral Delivery Advantage For Rybelsus

But not all diabetes drug marketers feel that way. Novo Nordisk AS is following a familiar playbook in the diabetes arena in that it hopes a delivery advantage will help find a niche for its recently-approved Rybelsus (semaglutide) in the crowded market. Rybelsus will be the first oral GLP-1 agonist and its list price is on par with Novo's injectable semaglutide, Ozempic, at around $9,200 a year.

However, it has a considerably higher price than other oral antidiabetics in the SGLT-2 inhibitor or DPP4 inhibitor classes, prompting speculation that it may need attractive rebates to be competitive. *(Also see "Novo Nordisk's Oral Rybelsus Priced On Par With Injectable GLP-1s, But Big Discounts May Be Needed" - Scrip, 23 Sep, 2019.)*

An asssessment of Rybelsus released 9 December by the Institute for Clinical and Economic Review concludes the drug's higher estimated net price makes it less cost effective than oral SGLT-2 inhibitors like Eli Lilly and Boehringer Ingelheim International GmbH's Jardiance (empagliflozin), which have "similar benefits with fewer common side effects."

The price differential, as well as the expectation that Rybelsus will be prescribed more widely by primary care physicians than the injectable, will prompt cost concerns among payers and new strategies to manage access, predicted IPD Analytics director of clinical pharmacy Jeffrey Casberg.

"I think where we're going is potential [formulary] management here," Casberg said at a recent ICER advisory panel meeting on Rybelsus. IPD is a data, research and analytics firm focusing on the pharmaceuticals market.

Although diabetics typically start on metformin before advancing to other types of treatments, payers generally do not require step therapy beyond that for the GLP-1 agonists, he noted. "Right now, there are not many plans with steps on the GLP-1s. … Once you get through metformin, it's open season," he added. "If payers put the step in front of the GLP-1s, that would be a change."

Anthem Requiring Step Therapy For Rybelsus

One large national payer that has publicly posted its coverage criteria for Rybelsus appears to be doing just that, Casberg pointed out.

According to criteria posted in November for Anthem's commercial plans, Rybelsus is a non-preferred agent and coverage will only be approved if the member has failed on metformin and "has had a trial … and inadequate response or intolerance to one preferred GLP-s receptor agonist." Preferred GLP-1s include Ozempic and AstraZeneca PLC's Byetta (exenatide) and Byduroen (exenatide extended release).

Payer's "are worried about the costs from a lot of additional use from [primary care physicians]," Casberg noted. The GLP-1 agents are more expensive that the SGLT-2s or DPP4s but the fact that they have previously only been available as injectables "have created a barrier and so [they] haven't been utilized to a great degree."

Payers "now are forced to look at the diabetic oral category and potentially make some changes," he said. Another option for management would be to require members to step through the oral SGLT-2 or DPP4 agents first before coverage is approved for Rybelsus.

For Rybelsus, "coming in at a lower [list] price could have been a different theory for capturing the market. If it came in at $6,000 or $7,000, we would be having a different conversation. But since the price differential is so huge, we're stuck talking about step therapy and things like that," he concluded.

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