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US FDA Biologics Designation As Price Protection: Lilly Charts New Course With Retatrutide

by Cathy Kelly

An effort to change the US Food and Drug Administration's conclusion that its obesity treatment candidate retatrutide is a drug and not a biologic could give the product more time with unrestricted pricing in Medicare, among other benefits.

Eli Lilly and Company's recently filed *lawsuit* against the US Food and Drug Administration seeking to overturn the agency's refusal to designate the company's investigational obesity agent retatrutide a biologic may forge a new path toward extended market exclusivity and unfettered pricing.

Lilly filed the complaint 3 September in Indiana federal court after the agency declined the company's request to designate retatrutide as a biologic instead of a drug. (*See sidebar.*)

Retatrutide is a GLP-1/GIP/glucagon receptor triagonist in Phase III trials for obesity, osteoarthritis, obstructive sleep apnea, type 2 diabetes, and reduction of adverse cardiovascular and renal outcomes in patients with obesity. Lilly maintains the product's regulatory status differs from GLP-1 agonist drugs for obesity currently on the market because

Key Takeaways

- Lilly's effort to overturn the FDA's conclusion that retatrutide is not a biologic could extend the agent's market exclusivity, as well as the time until it is subject to Medicare price negotiation.
- The product's status as a biologic would give retatrutide an advantage over GLP-1 agonist drugs for obesity like Novo

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of its composition.

By seeking to reverse the FDA's judgement, the suit attempts to leverage the newly created opportunity offered by the Supreme Court's June decision in *Loper v. Bright*, which overturned the *Chevron* doctrine of court deference to federal agencies. The decision improved the chances that manufacturers could successfully challenge some FDA decisions. (Also see "*Deference No More: More Suits Against US FDA Coming After High Court Tosses Chevron Doctrine?*" - Pink Sheet, 28 Jun, 2024.)

Nordisk's Wegovy and Lilly's own Zepbound in terms of pricing power.

- Wegovy could be subject to a reduced price in Medicare as early as 2027, according to forecasts.

Lilly also hopes to reverse past legal precedent with its lawsuit. *Teva Pharmaceuticals USA Inc.* challenged the FDA's refusal to "deem" Copaxone (glatiramer acetate) a biologic based on considerations similar to those the agency applied to retatrutide and the court ruled in favor of the agency based on the *Chevron* defense in late 2020. (Also see "*Copaxone Legal Fight May Finally Be Over As Court Finds The MS Treatment Is Not A Biologic*" - Pink Sheet, 5 Jan, 2021.)

Lilly Challenges US FDA Classification Of Obesity Drug Retatrutide, Citing Chevron Overturn

By Sue Sutter

10 Sep 2024

Determining what falls within the statutory definition of 'biological product' is an interpretative question that courts, rather than the agency, must resolve, Lilly said in a lawsuit repeatedly citing the US Supreme Court's June decision in *Loper Bright*.

Read the full article here

If Lilly prevails, legal challenges like the one it brought could be another option for brand companies seeking to deflect and delay lower priced follow-on competition, supplementing the patent-related maneuvers manufacturers typically have employed.

As a biologic, retatrutide could enjoy 12 years of market exclusivity instead of the five years given to drugs under the law. But perhaps more importantly, because patents could last longer than exclusivity, retatrutide as a biologic could have an easier time staving off lower-priced biosimilars than as a drug fending off generics, due to in part to differences in patent disclosure rules.

Biologics Fare Better Under Medicare Price Negotiation Regime

Retatrutide also would have a longer period of unrestricted pricing in Medicare as a biologic than as a small molecule drug. Under the Inflation Reduction Act, biologics could be subject to a

Medicare-negotiated price 13 years after approval, compared to nine years for small molecule agents.

Lilly's pursuit of a biologic designation for retatrutide began in November 2023, three months after the US Centers for Medicare and Medicaid Services announced the first 10 drugs subject to the Medicare price negotiation program.

Lilly was not directly involved in the first round of negotiations, although it co-markets *Boehringer Ingelheim GmbH*'s Jardiance (empagliflozin), one of the drugs that was subject to the process. CMS disclosed the final prices for the drugs in late August. (Also see "*A Better Deal: Medicare Discounts Surpass Estimated PBM-Negotiated Rebates*" - Pink Sheet, 16 Aug, 2024.)

Wegovy's Influence On Lilly's Suit

The significance of those extra years of pricing freedom for retatrutide in the anti-obesity category is underscored by the likelihood that *Novo Nordisk A/S*' blockbuster small molecule obesity drug, Wegovy, will be subject to a negotiated price in Medicare Part D in 2027. (Also see "*Medicare Negotiation Round Two Will Be Dominated By Oral Cancer Drugs, Researchers Predict*" - Pink Sheet, 16 Jul, 2024.)

If its price is negotiated, Wegovy will have been approved for only six and a half years when that price is implemented. Wegovy could be subject to the process because it contains the same active moiety (semaglutide) as Novo's older version for diabetes, Ozempic.

Lilly also markets the same active moiety, tirzepatide, in two separate products for diabetes and obesity. Mounjaro and Zepbound were approved in May 2022 and November 2023, respectively. But because they are the same drug, they could face a negotiated price at the same time, likely in 2032.

Medicare does not cover treatments for obesity alone but will cover drugs for related conditions, like cardiovascular health, in obese patients. Novo has obtained a cardioprotective indication for Wegovy (Also see "*US Medicare Plans 'Can' Cover Wegovy, CMS Says, But Will They?*" - Pink Sheet, 26 Mar, 2024.), and Lilly is pursuing a CV claim for Zepbound.

Those changes will allow for coverage of the drugs while Congress writes legislation requiring Medicare reimbursement for obesity agents. (Also see "*US House Bill Would Cover Obesity Drugs For Only Sliver Of New Medicare Enrollees*" - Pink Sheet, 27 Jun, 2024.)

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