



June 15, 2026

VIA ELECTRONIC SUBMISSION
Oregon Prescription Drug Affordability Board
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Eli Lilly and Company

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RE: Oregon Prescription Drug Affordability Board (PDAB): June 17, 2026, Meeting Materials — Draft Drug Review Reports for Mounjaro® and Humulin® R U-500

Eli Lilly and Company (“Lilly”) appreciates the opportunity to provide our perspective on the Oregon PDAB (“the Board”) meeting materials, which include the Draft Drug Review Reports (“the Reports”) for our products Mounjaro® (tirzepatide) and Humulin® R U-500 (human insulin).¹ Lilly is one of the country’s leading innovation-driven, research-based pharmaceutical and biotechnology corporations, committed to equitable and affordable access to our medicines so that our innovations can transform more people’s lives.

Lilly shares the Board’s goal of improving patient outcomes by making effective treatments accessible. However, price controls do nothing to make medicines more affordable for patients and any actions to meaningfully address affordability will require targeting underlying incentives in the pharmaceutical supply chain in need of reform, rather than misguided policies like UPLs. We continue to have serious concerns about the data and methodology underpinning the Board’s affordability review process. To that end, Lilly urges the Board to take into consideration the recommendations and concerns outlined below in its review of Mounjaro® and Humulin® R U-500.

Lilly is Committed to Patient Affordability

Throughout our 150-year history, Lilly has worked to address some of the most pressing health challenges facing humanity, including diabetes, depression, cancer, and obesity. Today, more than 71 million people are estimated to use a Lilly medicine. Our commitment to patients and society goes beyond the medicines we make, and we are committed to equitable and affordable access to our medicines so that our breakthroughs can transform more people’s lives.

Mounjaro® is Affordable in Oregon

The primary focus of any cost review by the Board should be on patients, and Mounjaro® is broadly affordable for Oregon patients. The Board’s own data shows that patient out-of-pocket costs are affordable: a median of \$30 per claim and \$135 per enrollee across all payers, with Medicaid enrollees paying \$0.² Affordability challenges that may occur with Mounjaro® are

¹Oregon Prescription Drug Affordability Board. Mounjaro® (tirzepatide), Version 1.0, June 9, 2026. <https://dfr.oregon.gov/pdab/Documents/Mounjaro.pdf>; and Humulin® R U-500 (insulin human), Version 1.0, June 9, 2026. <https://dfr.oregon.gov/pdab/Documents/HumulinRU-500-2026.pdf>

²Mounjaro® (tirzepatide), Version 1.0, June 9, 2026, Table 3 (2024 APAC annual enrollee out-of-pocket cost).

most likely a function of restrictive plan benefit designs, such as high upfront deductibles or adverse formulary tier placement with high patient cost-sharing obligations.

Health plans design formularies which determine patients' out-of-pocket cost obligations. According to the Board's data, approximately 82 percent of plans submitting data require prior authorization for Mounjaro®, approximately 55 percent place it on a non-preferred tier, and approximately 4 percent do not cover it at all.³ Non-preferred tiers require patients to pay more for their medicine than if it were on the preferred tier. Patients subject to plan designs with large deductibles or high cost-sharing tiers are more likely to struggle to afford their medicines.

In these circumstances, Lilly helps to reduce patient out-of-pocket costs for commercially insured patients. Lilly offers a variety of affordability solutions through patient support programs and copay assistance, including a \$25 Mounjaro® savings card for eligible commercially insured patients.⁴

Humulin® R U-500 is Affordable in Oregon

For millions of people with diabetes, insulin is a life-saving medicine, and Humulin® R U-500 serves a narrow, high-need population of patients who require more than 200 units of insulin per day.⁵ For years, Lilly has implemented multiple insulin affordability solutions, including our Lilly Insulin Value Program to reduce patient out-of-pocket costs. Through the Lilly Insulin Value Program, all currently available Lilly insulins are available for \$35 a month out of pocket whether a person has commercial insurance or no insurance, regardless of the number of pens or vials they are prescribed in a month.⁶

In addition, the Board's own data confirms that Humulin® R U-500 is affordable for patients. Based on All Payer All Claims (APAC) reporting, which includes both public and private payers, the median patient out-of-pocket cost is \$0 per claim for a Humulin® R U-500 KwikPen, and the median annual out-of-pocket cost per enrollee is \$2 for a Humulin® R U-500.⁷

Lilly also donates medicines to charitable organizations such as the Lilly Cares Foundation, a separate 501(c)(3) tax-exempt Indiana nonprofit corporation. Lilly Cares provides Lilly medications for free to qualifying patients.⁸ Patients in households with annual adjusted gross incomes of up to 400 percent of the federal poverty level are currently eligible for free insulin through Lilly Cares (currently \$62,600 for an individual or \$128,600 for a family of four).⁹ In

³Id., Table 27 (Plan design analysis from 2024). <https://dfr.oregon.gov/pdab/Documents/Mounjaro.pdf>

⁴ <https://mounjaro.lilly.com/savings-coverage>

⁵Humulin® R U-500 (insulin human), Version 1.0, June 9, 2026, "Estimated price for therapeutic alternatives" (no clinically appropriate therapeutic alternatives identified).

⁶Eli Lilly: Lilly Insulin Value Program <https://investor.lilly.com/news-releases/news-release-details/new-35-co-pay-now-available-through-lilly-insulin-value-program>

⁷Humulin® R U-500 (insulin human), Version 1.0, June 9, 2026, Tables 3, 34, and 35 (2024 APAC enrollee out-of-pocket cost).

⁸Lilly Cares Foundation. Available Medications. <https://www.lillycares.com/available-medications>.

⁹Lilly Cares Foundation. <https://www.lillycares.com/how-to-apply#check-eligibility>.

2025, Lilly Cares provided \$37.17 million in medication value to 1,179 patients served in Oregon.¹⁰

State health care system entities can already access Humulin® R U-500 at deeply discounted prices. The Oregon Medicaid Program receives substantial rebates for insulin products under the Medicaid Drug Rebate Program (MDRP).¹¹ According to MACPAC analysis of fiscal year 2020 data, brand-name drugs averaged total rebates of 61.6 percent, consisting of a basic rebate averaging 38.3 percent and inflation-related rebates averaging 23.3 percent.¹² Furthermore, Lilly offers supplemental rebates to Oregon and other state Medicaid programs, guaranteeing an affordable net unit price beyond that which is required under the MDRP.

Mounjaro® and Humulin® R U-500 Provide Value to Patients and the Health System

Any assessment that informs an affordability review should also account for clinical value and the medical costs that effective treatment can avert. Diabetes is among the costliest chronic conditions in the United States, with an estimated \$3 billion in annual expenditures in Oregon alone.¹³

Clinical evidence cited by the Reports reflects this value. Across five Phase 3 SURPASS trials, Mounjaro® demonstrated superior results in glucose control and weight reduction, including HbA1c reductions of roughly 1.9 to 2.6 percent and the highest weight-loss efficacy in its class. Clinical guidelines recommend GLP-1 receptor agonists as a first-line option for appropriate patients.¹⁴

In addition, insulin remains a life-sustaining therapy for people with diabetes, and Humulin® R U-500 serves a particularly high-need group: patients with severe insulin resistance who require more than 200 units of insulin per day, for whom standard-concentration U-100 insulins would mean impractically large or frequent injections.¹⁵ Uncontrolled diabetes can lead to serious and costly health complications, such as heart disease, painful neuropathy, blindness, kidney disease/failure, and lower-extremity amputations. Innovations in insulin have led to new medicines that serve a wide range of patient needs, enabling better adherence to treatment and avoiding serious complications and hospitalizations.

¹⁰ Lilly Cares Foundation. https://www.lillycares.com/assets/pdf/lilly_cares_2025_state_level_data.pdf

¹¹The Medicaid rebate formula ensures that state Medicaid programs, including the Oregon Medicaid Program, access the Medicaid Best Price. Lilly also offers supplemental rebates to state Medicaid programs.

¹²Medicaid and CHIP Payment and Access Commission (MACPAC). Trends in Medicaid Drug Spending and Rebates. October 2022. <https://www.macpac.gov/publication/trends-in-medicaid-drug-spending-and-rebates/>.

¹³American Diabetes Association. The Burden of Diabetes in Oregon
<https://diabetes.org/sites/default/files/2025-08/oregon-diabetes-08-26-25.pdf>

¹⁴Mounjaro® Report, “Clinical information based on manufacturer material” (SURPASS trials) and “Therapeutic alternatives” (American Diabetes Association, Standards of Care in Diabetes—2024, recommending GLP-1 receptor agonists as a first-line option for appropriate patients)
<https://dfr.oregon.gov/pdab/Documents/Mounjaro.pdf>

¹⁵U.S. Food & Drug Administration, Humulin® R U-500 (insulin human) Prescribing Information (indicated to improve glycemic control in adult and pediatric patients with diabetes mellitus requiring more than 200 units of insulin per day). https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/018780s135s152lbl.pdf.

The Report identifies no clinically appropriate alternative for the narrow patient population that Humulin® R U-500 serves. Providers have voiced serious concerns about the impact of PDABs and risks to patient care, including from nonmedical switching.¹⁶ The risks to patient health of nonmedical switching are well documented and include increased likelihood of adverse events, reduced adherence, and long-term complications.¹⁷

Data Quality Concerns Undermine the Board’s Affordability Review Process

We remain concerned about the data the Board is relying upon in its affordability reviews, independent of any ultimate affordability conclusion. We address the principal data quality concerns below.¹⁸

Key inputs are drawn from a limited carrier-submitted dataset that may be unrepresentative.

For Mounjaro®, the carrier data call captured 16,564 claims, compared with 55,891 claims in APAC, meaning it represents roughly 30 percent of statewide claims.¹⁹ Because that subset reflects only a minority of statewide utilization, the net-pricing and concession figures derived from it cannot be assumed to hold across the claims that make up the balance of APAC.²⁰

For Humulin® R U-500, the carrier data rest on still smaller samples: 274 claims and 73 enrollees for the concentrated vial, and 344 claims and 77 enrollees for the KwikPen, against APAC totals of 541 and 2,672 claims respectively.²¹ Yet two parameters central to the Board’s scoring rubric—price concessions and formulary/access status—appear to be derived solely from this carrier-submitted dataset, which is limited to fully insured commercial plans and excludes ERISA self-insured plans (covering roughly one million Oregonians), Medicaid, and Medicare. Drawing rubric scores from a small, non-representative sample risks bias and inaccuracy and, at a minimum, warrants explicit caveats and validation before the data inform the Board’s affordability determination.

Both Reports contain inconsistencies and key errors that compromise the review process.

Both Report rubrics report the discount percent in place of the share of claims receiving a concession: the “Price concessions” domain of the rubric (Table 4) is described as the share of claims that “receive rebates or price concessions.” But the value entered is not the share of claims but rather the average percent discount.

For Mounjaro®, the rubric states “52.4% claims receive rebates or price concessions” but Table 15 shows that 52.4 percent is the percentage of discount, while the share of claims actually

¹⁶ Value of Care Coalition. Specialty Doctor Survey Reveals Concerns about PDABs.

<https://valueofcarecoalition.org/blog/specialty-doctor-survey-reveals-concerns-about-pdabs/>

¹⁷ Ellingson L. Position on non-medical switching for diabetes patients. *J Diabetes Metab Disord Control*. 2017;4(5):138-139. DOI: [10.15406/jdmdc.2017.04.00123](https://doi.org/10.15406/jdmdc.2017.04.00123)

¹⁸ See Letter from Lilly to Board (October 13, 2025); Letter from Lilly to Board (January 19, 2026)

¹⁹Mounjaro® Report, Table 15 (carrier data call: 16,564 claims; 6,286 enrollees) and Table 20 (APAC: 55,891 claims; 9,920 enrollees).

²⁰Mounjaro® Report, Table 27 (carrier-reported plan design) and Table 20 (APAC claims by line of business).

²¹Humulin® R U-500 Report, Table 21 (carrier data call: 274 claims / 73 enrollees (vial); 344 claims / 77 enrollees (KwikPen)) and Table 15 (APAC: 541 claims (vial); 2,672 claims (KwikPen)).

receiving a concession is 92.3 percent.²² For Humulin® R U-500, the rubric reports “20.9% claims receive rebates or price concessions” for the KwikPen, but Table 21 identifies those as discount figures, with the true claim shares being 87.2 percent for the KwikPen.²³ In each case, the mislabeling understates how broadly concessions apply. Because the rubric is a structured input to the Board’s affordability determination, this error risks skewing the Board’s review and conclusions. In addition, the Mounjaro® Report understates the total of price concessions by more than \$8 million. The Report narrative states total price concessions of “approximately \$2,183,220” while the table on the same page reports \$10,599,425.²⁴

As of May 2026, Humulin® R U-500 is only available in KwikPen formulation, making data on cost and price concessions on the vial formulation from previous years no longer relevant. The Report also confusingly reports WAC in a form completely disconnected from the necessary dosing patients actually require without any context or explanation.²⁵ In addition, the Report cites the prescribing information for an unrelated product (Eliquis/apixaban, a Bristol-Myers Squibb anticoagulant) as the source for its drug-information table.²⁶

Patient data reported for Humulin® R U-500 also raises patient privacy concerns. Tables 11 through 13, which identify patient race and ethnicity, include patient counts of five or fewer. The Centers for Medicare and Medicaid Services (CMS) suppresses Medicaid State Drug Utilization Data (SDUD) cells with fewer than eleven prescriptions, citing the Federal Privacy Act and the HIPAA Privacy Rule.²⁷ It is critical for the Board to correct these errors and data issues before proceeding any further.

Methodological Concerns Remain Unaddressed

As in prior comments²⁸, we reiterate our concerns about the methodology the Board employs to measure and define affordability.

The Board has not meaningfully defined “affordability.” It remains unclear whether the primary focus of the review is patient cost-sharing or system cost. Without a consistent definition, reviews risk being applied in an arbitrary and inconsistent manner, stakeholder input is inhibited, and it becomes virtually impossible to determine whether a medicine creates an

²² Mounjaro® review, Table 4, p. 6; Table 15, p. 16

²³ Humulin® R U-500 review, Table 4, p. 5; Table 21, p. 15

²⁴ Mounjaro® review, Table 15, p. 16

²⁵ Humulin® R U-500 Report Table 16 “600 U refers to how many units a patient needs in 30 days” However, the correct indication — stated on pages 7 and 24 — is for patients “requiring more than 200 units of insulin per day.” That’s >6,000 units per 30 days, not 600.

²⁶ Humulin® R U-500 Report, Table 5 source note (citing Eliquis (apixaban) prescribing information, Bristol-Myers Squibb Company); and compare “Drug indications – Limitation of use” (“has been determined”) with “Comparative clinical efficacy” (“has not been determined”).

²⁷ <https://www.cms.gov/files/document/medicaid-state-drug-utilization-data-field-descriptions.pdf>

²⁸ See Letter from Lilly to Board (October 13, 2025); Letter from Lilly to Board (January 19, 2026)

“affordability challenge.”²⁹ As noted at the outset, patient affordability should be the focus of any cost review.

The Board’s reliance on total gross spending creates bias and conflates cost with utilization. The use of total gross spending data biases selection toward medicines with high aggregate spending that treat large populations of individuals with chronic conditions, further confirmed by the fact that the Board continues to review products with indications for diabetes, a chronic condition impacting millions of Americans. For Humulin® R U-500, the per-enrollee totals are a direct function of disease severity, not unit price: the product is indicated for patients requiring more than 200 units of insulin per day. Affordability determinations should reflect estimated net spending on a per-patient basis, inclusive of any medical cost offsets attributable to the drug that ultimately accrue to state purchasers.

Wholesale Acquisition Cost (WAC) is a flawed measure disconnected from the actual prices paid by payers. Although the Board may consider WAC, its statutory directive is to identify whether a drug may create affordability challenges for health care systems or high out-of-pocket costs for patients—a determination that cannot reasonably rest on list price.³⁰ WAC does not represent the final net cost of a drug because rebates and other price concessions reduce the net cost incurred by payers, including state payers. The Board’s own data confirms this: for Mounjaro®, the average price concession was 52.4 percent.³¹ For Humulin® R U-500, WAC has been flat for seven years while inflation rose, and the acquisition cost is below WAC. It is unclear how WAC could increase the cost to the health care system when WAC does not measure a net price to any payer.

The Board Provides Insufficient Timelines for Meaningful Public Comment

The Board must also allow sufficient time for meaningful public and stakeholder participation in the affordability review process before rendering decisions.³² The Board’s practice of setting unreasonably short comment periods continues to raise significant concerns about the ability of stakeholders to meaningfully review materials and provide comment, including its legal obligations to establish a process for patient and caregiver outreach and input.³³

The Board Should Continue to Promote Policies that Actually Address Patient Affordability

Lilly is pleased that some of the policy recommendations adopted in the Board’s 2025 Report would meaningfully address issues in the pharmaceutical payment system without inviting the

²⁹Oregon Prescription Drug Affordability Board. “OAR 925-200-0020 conducting an affordability review.” <https://dfr.oregon.gov/pdab/Documents/OAR-925-200-0020.pdf>.

³⁰OAR 925-200-0010.

³¹Mounjaro® (tirzepatide), Version 1.0, June 9, 2026, Tables 15 and 16 (net cost price concession estimates; mean price concessions across market types).

³² OAR 925-200-0020(k)

³³ Or. Rev. Stat. § 646A.694(3); OAR 925-200-0020(2)(k)(A).

unintended consequences inherent in price-setting schemes.³⁴ The Board should continue to recommend reforms that address the warped supply-chain incentives that expose patients to higher cost-sharing obligations, which would enable lower costs at the point of sale and create the conditions for list and net price parity. Notably, the patient feedback summarized in the Reports describes coverage and cost barriers due to these warped incentives, indicating patients continue to face barriers to accessing needed medicines.

Lilly appreciates the opportunity to respond to the Board materials. We value the Board's shared commitment to improving prescription drug access and patient affordability, and we believe Lilly medicines like Mounjaro® and Humulin® R U-500 positively contribute to the health and well-being of patients in Oregon.

Sincerely,



Rachel Dolan
Senior Director, US Public Policy
Eli Lilly & Company

³⁴Oregon Prescription Drug Affordability Board, 2025 Annual Report, at 30.
<https://dfr.oregon.gov/pdab/Documents/reports/PDAB-Annual-Report-2025.pdf>.