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VIA ELECTRONIC FILING

Mr. Patrick Allen
Director
Oregon Health Authority
Health Policy and Analytics Medicaid Waiver Renewal Team
Attn: Michelle Hatfield
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Lilly USA, LLC

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**RE: Application for Renewal and Amendment Oregon Health Plan, Section 1115
Demonstration Waiver**

Dear Director Allen:

Lilly USA, LLC (Lilly) appreciates the opportunity to submit comments on the proposed application by Oregon Health Authority for renewal and amendment of the Oregon Health Plan (OHP) 1115(a) Demonstration Waiver. Lilly is one of the country's leading innovation-driven, research-based pharmaceutical and biotechnology corporations. Our company is devoted to seeking answers for some of the world's most urgent medical needs through discovery and development of breakthrough medicines and technologies, as well as through the analysis and distribution of health information. Ultimately, our goal is to develop products that save and improve patients' lives.

Lilly supports Medicaid beneficiaries' access to high quality health care and medicines and is concerned that the Oregon Health Authority's Section 1115 waiver, which proposes to impose a closed formulary and exclude important innovative drugs approved through the FDA instituted Accelerated Approval Program which would seriously limit patient access to medicines and is not permissible by law. Our primary arguments are as follows:

- The closed formulary may harm patients, reduce medication adherence, and will not result in a reduction in health care costs;
- Denied access of the FDA's accelerated approved drugs will significantly restrict patient access to innovative and complex medicines;
- CMS has rejected a nearly identical proposal by Massachusetts due to the violation of the existing Social Security Act law. Provisions of the Medicaid Drug Rebate Statute cannot be waived under Section 1115 of the Social Security Act;
- The closed formulary and medication coverage restrictions are not permitted under Section 1115 of the Social Security Act as they sever the compact in the Medicaid Drug Rebate Statute; and,
- Cost containment options and tools are available to help control drug expenditures and mitigate risk.

Lilly also supports the comments provided to the Centers for Medicare & Medicaid Services (CMS) by the Pharmaceutical Research and Manufacturers of America (PhRMA) and the Biotechnology Industry Organization (BIO).

I. Oregon Health Plan Closed Formulary Could Harm Patients, Reduce Medication Adherence, and Will Not Result in a Reduction in Health Care Costs

The Oregon Health Plan, Section 1115 waiver, proposes to restrict access to one drug per class with intent to exclude drugs approved through the FDA's accelerated approval process. Implementation of both policies would hinder patients' access to a diverse range of innovative treatment options that could best serve their needs, including the individual plaintiffs in the case of *McCutchen v. Becerra* (pending, D.D.C.). This is particularly troubling given the vulnerability of the Medicaid population. Non-elderly Medicaid beneficiaries are more likely to be in poor health than those with private insurance.¹ Children covered by Medicaid are also more likely to be in fair or poor health as well as have a higher prevalence of certain behavioral health conditions than those with private coverage.² Unlike patients with commercial or Medicare insurance, Medicaid patients do not have the ability to choose amongst various plans for coverage that better fits their individual health challenges, so the application of a commercial-like benefit design is wholly inappropriate in this context.

Moreover, research has shown that formulary restrictions can harm medication adherence³. In addition, they may have unintended consequences and result in increased costs. For example, a study found that formulary restrictions for Arizona Medicaid beneficiaries living with arthritis had unintended consequences including increasing hospitalizations and costing an additional \$900 annually per beneficiary. For these reasons, CMS should be highly skeptical of any proposal to limit Medicaid beneficiary access to necessary medications.

II. Restricting Access to Drugs Approved under FDA's Accelerated Approval Pathway Will Harm Patients Facing Greatest Unmet Need

For nearly 30 years, the Accelerated Approval pathway has facilitated approval of medicines that treat serious and life-threatening diseases and conditions for patients who have no adequate treatment options. Nearly 270 medicines have received accelerated approval,⁴ extending – even saving – patients' lives by providing earlier access to novel therapies than would have been possible using the traditional approval pathway.

Oregon's proposal to exclude drugs approved through the accelerated approval (AA) process is wholly inappropriate and reflects a substantial misunderstanding of FDA's drug approval process and evidentiary standards.⁵ Oregon suggests this proposal is part of an effort to "prioritize patient

¹ MACPAC, "MACStats: Medicaid and CHIP Data Book," December 2016, Available at: https://www.macpac.gov/wp-content/uploads/2016/12/MACStats_DataBook_Dec2016.pdf, cited in PhRMA letter to Secretary Sudders, August 15, 2017, footnote 58.

² MACPAC, "Chapter 4: Behavioral Health in the Medicaid Program—People, Use, and Expenditures," June 2015, Available at: <https://www.macpac.gov/wp-content/uploads/2015/06/Behavioral-Health-in-the-Medicaid-Program%E2%80%94People-Use-and-Expenditures.pdf>, cited in PhRMA letter to Secretary Sudders, August 15, 2017, footnote 59.

³ Happe LE, Clark D, Holliday E, Young T, "A Systematic Literature Review Assessing the Directional Impact of Managed Care Formulary Restrictions on Medication Adherence, Clinical Outcomes, Economic Outcomes, and HealthCare Resource Utilization," J Manage. Care Spec. Pharm. 2014; 20(7):677-84, cited in PhRMA letter to Secretary Sudders, August 15, 2017, footnote 72.

⁴ U.S. Food & Drug Admin., CDER Drug and Biologic Accelerated Approvals Based on a Surrogate Endpoint as of June 30, 2021, <https://www.fda.gov/media/151146/download>.

⁵ Separately, Oregon also mischaracterizes the 21st Century Cures Act, suggesting it was "intended to expedite the drug approval process by reducing the level of evidence required for drugs to reach the market and allowing

access to clinically proven, effective drugs.” Yet, drugs that have received accelerated approval must meet the same standards of safety and efficacy as a therapy that is approved under the traditional pathway. The difference between the two pathways is the type of endpoints that may be utilized in the clinical trials supporting approval. CMS itself recognized this in 2018 guidance when it stated, unambiguously, that accelerated approval drugs must be covered by Medicaid, like all other drugs:

Therefore, as with any other drug, if the drug is labeled by a manufacturer that has signed a Medicaid National Drug Rebate Agreement, and the drug meets the definition of covered outpatient drug, then the drug is covered by the Medicaid Drug Rebate Program (MDRP) and is to be covered by state Medicaid programs.⁶

Imposing policies that make it harder for patients suffering from serious or life-threatening conditions to access approved medicines would undermine the important policy goal behind accelerated approval – facilitating earlier patient access to approved therapies. Furthermore, there is no data to suggest that drugs that go through the AA pathway are driving spending for Medicaid. In fact, a recent analysis of Medicaid spending found that accelerated approval drugs consistently accounted for less than 1% of spending. Since passage of the Food and Drug Safety and Innovation Act which encouraged accelerated approval use for serious and life-threatening conditions in addition to oncology and HIV/AIDS, Medicaid spending on accelerated approval drugs remained steady at 0.6% to 0.8% a year.⁷

Denying Medicaid patients access to medicines approved under the Accelerated Approval pathway deprive some of the sickest patients, who are most in need of treatment, access to innovative, life-saving drugs.

III. CMS has rejected a nearly identical proposal by Massachusetts due to the violation of the existing Social Security Act law. Provisions of the Medicaid Drug Rebate Statute cannot be waived under Section 1115 of the Social Security Act.

In 2017, Massachusetts, MassHealth Section 1115 Demonstration Amendment suggested a similar proposal that failed to meet the intended goal of ensuring robust access to medically necessary drugs and ultimately excluded a vast number of FDA-approved drugs for vulnerable populations. The proposed demonstration amendment mischaracterized the FDA Approval Process, failed to consider the importance of individualized patient-centered care, and disregarded research that revealed the negative effects of closed formularies. Furthermore, CMS responded to the Massachusetts waiver amendment by issuing “Release No. 185” stating that a drug approved by the FDA under the accelerated approval pathway must be covered by state Medicaid programs, if the drug meets the definition of “covered outpatient drug” as found in Section 1927 of the Social Security Act and has signed a Medicaid National Drug Rebate Agreement.⁸

doctors, patients, and payers to decide whether to purchase them.” This is simply false. Nothing in the Cures Act altered FDA’s strict approval standards. The legislative history also reflects an ongoing commitment to maintain these high standards. *See e.g.*, House E&C Subcommittee on Health Ranking Member Frank Pallone (Nov. 30, 2017) (“At FDA, the Cures Act aims to bolster the medical product review process in order to get treatments to patients faster while also maintaining FDA’s gold standard for safety and effectiveness.”).

⁶ CMS, MDRP Notice for State Technical Contacts, Release No.185, at 1 (June 27, 2018), [state-rel-185.pdf](#).

⁷ Thorpe, K. E., PhD, & Holtz-Eakin, D., PhD. (2021). Limiting Medicaid Access to Accelerated Approval Drugs: Costs and Consequences. *American Journal of Managed Care*.

⁸ CMS State Release No. 185, June 27, 2018.

Social Security Act § 1115(a)(1) provides that, “[i]n the case of any experimental, pilot, or demonstration program which, in the judgment of the Secretary, is likely to assist in promoting the objectives of [Medicaid or certain other programs], in a state or states— (a) the Secretary may waive compliance with any of the requirements of section 402, 454, 1402, 1602, or 1902 . . . to the extent and for the period he finds necessary to enable such state or states to carry out such project.” SSA § 1927 (the Medicaid rebate statute, codified at 42 U.S.C. § 1396r-8 [SSA 1927’s] is not on the list of waivable provisions. Accordingly, the D.C. Circuit held in *PhRMA v. Thompson*, CMS had no authority to waive requirements of the rebate statute under § 1115. *PhRMA v. Thompson* is the only case that has addressed whether SSA § 1115 permits waivers of rebate statute requirements. The D.C. Circuit’s ruling has never been overturned or questioned by later cases⁹.

No later cases have overturned this decision. Other courts have agreed that benefit cuts are not valid “demonstrations” under federal law. For example, in the context of a work requirement to qualify for food stamps, the federal court of appeals for the Ninth Circuit emphasized that “[a] simple benefits cut, which might save money but has no research or experimental goal, would not satisfy th[e] criteria [of] ha[ving] a research or demonstration value.” That logic is applicable here, as all the Oregon Health Plan “demonstration” seeks to test is whether cutting benefits by limiting the drugs that are covered by the state, results in “savings.” This is not a good-faith demonstration exercise but is simply an effort for the state of Oregon to shirk its obligations under the Medicaid Drug Rebate program.

Any 1115 demonstration project must be “likely to assist in promoting the objectives of [Medicaid].” Based on the language of the Medicaid statute, courts generally describe Medicaid’s objectives as providing medical assistance to those whose income and resources are inadequate to meet the costs of such care. Allowing a waiver of the drug coverage requirements in the rebate statute would not promote those purposes. Instead of enabling states to assist people who cannot afford necessary medical care, such a waiver would reduce beneficiaries’ access to medicines and adversely affect their health in two ways: directly, by permitting the State to cut back on drug coverage; and indirectly, by eliminating or curtailing manufacturers’ incentive to participate in the Medicaid rebate program—a program that has successfully provided Medicaid beneficiaries “access to the same range of drugs that the private patients of their physicians enjoy” since its start in 1991. The rebate program could unravel quickly if one selective waiver of the rebate statute’s coverage requirements were granted, as other states would likely seek the same waiver once the precedent was established; this would be a serious setback for Medicaid objectives and for beneficiaries’ health and well-being.

IV. The Medicaid Drug Rebate Statute (Section 1927) Represents a Two-Part Agreement That Cannot be Severed by Waiving the Coverage Requirements Alone

Even if CMS could waive the Medicaid Drug Rebate Statute, it could not waive only the statute’s coverage requirements while leaving in place the obligation that manufacturers pay rebates on Medicaid utilization. The existing statute requires states to cover all products of manufacturers with Medicaid rebate agreements. This coupling of the rebate and coverage requirements was described by a key sponsor of the Medicaid Drug Rebate Statute, Congressman Henry Waxman, as a “government-industry compact.” CMS has also explained the connection between the coverage and rebate requirements as follows:

⁹ *PhRMA v. Meadows*, 304 F. 3d 1197 (11th Cir. 2002); *PhRMA v. Thompson*, 362 F. 3d 817, 823-24 (D.C. Cir. 2004).

[The Medicaid Drug Rebate Statute] sets forth requirements for covered outpatient drugs, whereby drug manufacturers must pay statutorily defined rebates to the states through the Medicaid drug rebate program. In return, any state that provides payment for drugs must cover all covered outpatient drugs, which may include appropriate limitations on amount, duration, and scope, for the drug manufacturers that participate in the Medicaid drug rebate program.

As elucidated by CMS 2013 regulatory preamble regarding Medicaid coverage: “[D]rug manufacturers must pay statutorily-defined rebates to the states through the Medicaid drug rebate program. In return, any state that provides payment for drugs must cover all covered outpatient drugs, which may include appropriate limitations on amount, duration, and scope, for the drug manufacturers that participate in the Medicaid drug rebate program.” CMS’s respect for this statutory compact was evident when, in 2018, CMS rejected Massachusetts’ request to establish a closed formulary under the state plan. This policy “would have allowed the State to continue to collect manufacturer rebates under Section 1927, while enabling the State to exclude certain drugs from coverage,” thereby rupturing the statute’s careful balance. CMS expressed its willingness to “consider a demonstration” that would provide “coverage of outpatient drugs under the expenditure authority in section 1115(a)(2),” thereby giving the state the “ability to exclude certain Medicaid covered outpatient drugs from coverage.”

Hence, CMS has recognized and validated the link between the coverage and rebate requirements. It therefore follows that, were Oregon to fail to comply with the coverage requirements of the Medicaid Drug Rebate Statute through implementation of the closed formulary and other proposed coverage restrictions, it would not be in compliance with the statute. This would thereby remove manufacturers’ obligation to pay rebates under the Medicaid Drug Rebate Statute. Instead, manufacturers could negotiate price concessions directly with the state.

V. Oregon Has Access To Cost Containment Options And Tools Are Available To Help Control Drug Expenditures And Mitigate Risk

The benefits of the statutory Medicaid rebate program are significant. Of the many services Oregon provided for its Medicaid beneficiaries in FFY2019, only 2.9% of the total budget was spent on retail brand and generic drugs. Brand drugs alone were only 1.4% of the total Medicaid budget. Furthermore, manufacturers rebated \$403 million back to Oregon and the federal government, 57% of the total Medicaid spending on drugs.

The states’ tools to save money on prescription drugs provide it with meaningful chances to reduce prescription drug spending. For example, states may: 1) impose prior authorization requirements on any drug, subject to certain timing and supply requirements; 2) impose restrictions authorized by an agreement with a drug manufacturer; 3) create Medicaid formularies and exclude drugs from such formularies under certain specified conditions; 4) create Preferred Drug Lists (PDLs) and may demand supplemental rebates as the price for including a drug on the PDL, among other options; and 5) implement reinsurance mitigation risk programs to decrease the pharmacy expenditures for high-cost enrollees and stabilize premiums.

Furthermore, as noted above, the closed formulary proposal would disrupt the compact of the Medicaid Drug Rebate Statute. This could result in the State losing access to statutorily defined

rebates, which could lead to increased costs to the State for prescription drugs and ultimately result in access challenges for Medicaid beneficiaries.

Thank you for the opportunity to submit comments in opposition to Oregon's 1115 Demonstration Waiver proposal. We respectfully request that CMS deny these portions of the request as they will pose a serious threat to patient access to health care and could result in higher health care costs. If you have any questions, please do not hesitate to contact me at oneail_shawn@lilly.com.

Sincerely,

A handwritten signature in dark ink, appearing to be 'Shawn O'Neil', with a stylized, sweeping flourish extending to the right.

Shawn O'Neil
Vice President, Government Affairs