Dear Chair and Members of the Board,

On behalf of the Rare Access Action Project (RAAP), we respectfully submit the following comments regarding the Board's consideration of Keytruda under Oregon's prescription drug affordability review process.

RAAP strongly opposes the advancement of an affordability review for Keytruda as doing so appears inconsistent with Oregon's existing statutory and regulatory framework governing the Board's authority. Oregon administrative rules clearly provide that a prescription drug designated by the U.S. Food and Drug Administration (FDA) for a rare disease or condition is not subject to an affordability review. Keytruda includes FDA-designated orphan indications and therefore falls within the scope of Oregon's rare disease exemption.

The rare disease exemption exists for important policy reasons. It helps protect patient access to critical therapies, preserves incentives for continued research and innovation, and reduces the risk of unintended barriers for patients living with serious and often life-threatening conditions for which treatment options may be limited or nonexistent. Maintaining these protections is essential to ensuring that vulnerable patient populations are not adversely impacted by state-level affordability actions.

Applying the exemption inconsistently or narrowing its interpretation would create significant uncertainty for patients, providers, researchers, and manufacturers across the rare disease community. It would also undermine the clear intent of the rule itself, which states:

"A prescription drug that is designated by the United States Food and Drug Administration (FDA), under 21 U.S.C. 360bb, as a drug for a rare disease or condition, is not subject to an affordability review."

RAAP is additionally concerned that advancing reviews of therapies that qualify for this exemption could establish a troubling precedent for future state actions affecting orphan-designated treatments. While Oregon does not currently maintain Upper Payment Limit (UPL) authority, proposals to establish such authority continue to emerge during legislative sessions. RAAP remains concerned that policies such as UPLs can create unintended access barriers that negatively affect patients who rely on specialized therapies.

For these reasons, RAAP respectfully urges the Board to follow both the letter and intent of Oregon's rare disease exemption and decline to move forward with an affordability review of Keytruda.

Thank you for your consideration and for the opportunity to provide these comments.

Sincerely,

Michael Eging
Executive Director
Rare Access Action Project