

US Public Policy



# Barriers to outcomes-based contracts for pharmaceuticals

**Leigh Anne Leas**  
**VP and US Country Head Public Policy**

# Delivering value to patients and the healthcare system

- Novartis is working to deliver better health outcomes for patients and society.
- Over the past several years, we have engaged in a number of different pricing models which underscore our:

1 Confidence in the efficacy of our products

2 Support the shift from volume to value, where appropriate

3 Commitment to align incentives with the tangible outcomes of our innovative medicines

# Our experience with outcomes-based agreements

- Novartis has entered into outcomes-based agreements with a number of major payers for several of our products
- These outcomes-based agreements result in price reductions to payers if the drugs do not perform as anticipated
- We have negotiated such agreements for:



# Legal and regulatory barriers



## Anti-kickback Statute

- Requires that contracts based on delivering results do not inadvertently trigger anti-kickback liability
- Particularly challenging when contracts involve data analysis or medication adherence



## Adherence to Product Label

- Outcomes-based contracts must be defined within the narrow window of the product's FDA-approved label for the indication
- Additional Phase 3 trial planning required to anticipate the inclusion of patient types or financial outcomes suitable for a future OBC arrangements



## Government Price Reporting

- Ensuring that government price reporting requirements (Best Price, ASP, etc) do not inadvertently trigger a negative pricing impact in an outcomes based contract. Can limit the amount of innovation and risk in these arrangements

# Questions