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:

  - **Entresto** (sacubitril/valsartan) tablets
  - **Gilenya** (fingolimod)
  - **Tasigna** (nilotinib) 100mg, 200mg capsules
  - **Kymriah** (tisagenlecleucel) Suspension for IV infusion
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