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THIRD PLENARY:
Risk Sharing Agreements: Country Experiences, Challenges, and Lessons Learned

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RISK SHARING AGREEMENTS: COUNTRY EXPERIENCES, CHALLENGES, AND LESSONS LEARNED

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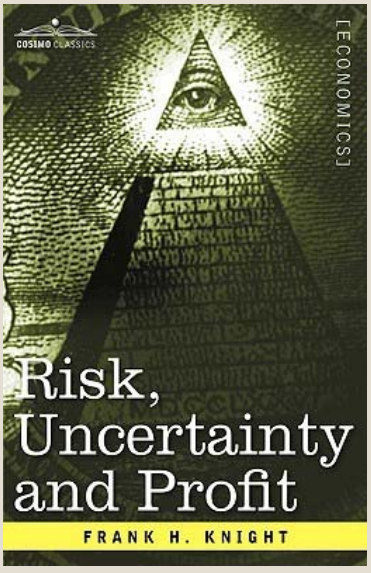
Disclaimer

- JM is an employee of Janssen-Cilag but views and opinions expressed in this presentation do not necessarily reflect the official company position.



Risk

Assumptions

- New product that could prolong life by one year in perfect health.
- WTP 30,000 USD per year
- Response Rate **50%** (risk).

Traditional Pricing

- Price per patient: 15,000 USD

"Risk Sharing"

- Price per Responder: 30,000 USD
- Price per Non-responder: 0 USD
- Average price per patient: 15,000 USD

- Risk sharing is present in both pricing schemes
- "risk sharing" involves higher transaction costs (cost of contracting, monitoring etc.) than "mixed price"

Uncertainty

Assumptions

- As before
- Response Rate ?%

Conceptually, could work, however, if performance of a drug is subject to 'Knightian uncertainty', more data are warranted and RSA not necessarily an apropriate instrument.

Possible solution: Link data collection of RSA with R&D, and use data for adaptive (Baysian) trials or to assess real world effectiveness.

In 2006, Netherlands, introduced a coverage with evidence development (CED) policy for expensive medicines to reassess CE with RWD.

"By the end of 2011, 26 expensive drugs for 34 indications were on the positive list of this policy regulation, as well as 10 orphan drugs. By that time, five drugs had reached the reassessment phase after 4 years. For two of these, no reassessment dossier was submitted to the CVZ, and subsequently these drugs were taken off the positive list and the additional funding for these drugs within hospitals was stopped. For the other three drugs, the dossiers were submitted to the CVZ in 2011, presenting the effectiveness, cost-effectiveness, and actual use based on 4-year findings. None of the dossiers presenting real-world effectiveness, cost-effectiveness, and actual use was considered to be of adequate quality." (Garrison et al. 2013)

Implications

- RSA do have a role when they can reduce uncertainty and can be used for evidence generation. For this, quality on technical infrastructure, data collection and data analytics must be high.
- Otherweise (in case of risk), RSA just increases transaction costs and do not lead to an increase of economic welfare.
- Possible application: CART

Germany, July 2018: Highest federal social judges declared “mixed prices “to be legal

GKV Spitzenverband

vfa. Die forschenden Pharma-Unternehmen

- **Darin Kottege** has over 7 years' experience across the Australian Pharmaceutical Benefits Scheme (PBS). The majority of which comes from his time in Australian Government Department of Health. He has been involved in the development and implementation of a wide range of policies, programs and reforms ensuring the ongoing sustainability of Australia's PBS. Darin was directly involved in the negotiations for multiple Agreements between the Commonwealth of Australia and the pharmaceutical supply chain. He also provided strategic policy advice and Government Budget impact forecasting to the Office of the Minister for Health.

  Darin has tertiary qualifications in health sciences including a Bachelor of Medical Science and a Graduate Certificate in Human Movement Science with a focus on biomechanics and exercise physiology. Darin is the Manager for Access & Funding Policy at Medicines Australia, the peak body representing research based pharmaceutical companies in Australia, where he collaborates with government on the development of sound policies to support access to prescription medicines for Australian patients.

- **Jang Sae Rak** is Deputy Director of Pharmaceutical Benefit Listing Division at Health Insurance Review and Assessm ent Service (HIRA) in South Korea. He works mainly in the areas of drug listing and pricing, price reassessment, and d rug utilization review at HIRA. Mr. Sae Rak also has experience in pharmaceutical industry, and he has the qualificat ion in pharmacy.

- **Gergana Zlateva** is a Vice President, Oncology Market Access at Pfizer Inc. Gergana' s team is responsible for leading global pricing and market access strategies for Pfizer's oncology medicines, working towards securing patient access to innovative treatments for challenging conditions. Prior to this role, Gergana was the Payer Insights and Access Cluster Lead for North America, and managed a team of colleagues supporting Pfizer's portfolio of patent protected and post-LOE products. During her 15-year tenure with Pfizer, Gergana has held various positions of increasing responsibility covering health economics, outcomes research, real world data, pricing, and reimbursement activities across several therapy areas and geographies. Gergana has led successfully business initiatives establishing new organizational models, capabilities, and process at various organizational levels. In her work, Gergana has a track record of partnering with different stakeholders and incorporating customers' perspective. Prior to joining Pfizer in 2003, Gergana worked for 5 years on public health, civil society, and business development programs with several United Nations agencies. Gergana holds a PhD in Economics from Fordham University, NY and a BA and MPA from Southern Illinois University, IL. Gergana's CV includes more than 60 peer-reviewed manuscripts cited over 2,000 times.