Preparing for Performance-Based Risk-Sharing Arrangements: An Academic Perspective

ISPOR 6th Latin American Conference

Sao Paulo, Brazil

September 17, 2017

Lou Garrison, PhD
School of Pharmacy, Univ. of Washington
Visiting Senior Fellow, Office of Health Economics, London,

Acknowledgments

- ISPOR Short Course material from Lou Garrison and Josh Carlson (University of Washington) and Adrian Towse (OHE)

- University of Washington (UW) Project Collaborators: Sean Sullivan, Josh Carlson, David Veenstra, Peter Neumann, Rick Carlson, Adrian Towse

- Sponsors of UW PBRSA Research Project: Novartis, Johnson & Johnson, GSK, GE Healthcare, Roche, Pfizer, Eli Lilly, Sanofi-Aventis, Abbott Laboratories, Amgen

- ISPOR PBRSA Task Force: Co-Chairs: Louis P. Garrison, Jr., Adrian Towse, England, UK; Members: Andrew Briggs, Gerard de Pouvourville, Jens Grueger, Penny Mohr, J.L. (Hans) Severens Paolo Siviero, Miguel Sleeper

The Question

- From the perspective of academia, what capacity building is necessary to build towards the comprehension and development of RSA in LAC region and how feasible is this?

Starting Point

Lack of Real-World Data: A Market Failure for Medicines as Global Public Goods

Current global health system has very weak incentives to measure performance after a medicine is on the market.

- This means that we do NOT operate as "learning health care systems."

Paying for Performance: A New Idea in 2007?

The New York Times

Business

WORLD | U.S. | N.Y. / REGION | BUSINESS | TECHNOLOGY | SCIENCE | HEALTH | SPORTS | OPINION

MEDIA & ADVERTISING | WORLD BUSINESS | SMALL BUSINESS | YOUR MONEY | DEALBOOK | MARKETS | RESEAR

Pricing Pills by the Results

Illustration by The New York Times

By ANDREW POLLACK
Published: July 14, 2007

SIGN IN TO E-MAIL OR SAVE THIS
PRINT
REPRINTS
SHARE

Drug companies like to say that their most expensive products are fully worth their breathtaking prices. Now one company is putting its money where its mouth is — by offering a money-back guarantee.

Johnson & Johnson has proposed that Britain's national health

Performance-Based Risk-Sharing Arrangements: A Variety of Names

- managed entry agreements (MEA)
- outcomes-based schemes
- risk-sharing agreements
- coverage with evidence development (CED)
- access with evidence development
- patient access schemes (PAS)
- conditional licensing
- pay-for-performance programs (P4P)
- And others?

PBRSA—Five Key Characteristics

1. ***There is a program of data collection*** agreed between the manufacturer (or provider, in some instances) and the payer..
2. ***This data collection is typically initiated during the time period following the regulatory approval*** (which may be full, conditional, or adaptive), and linked to post-launch coverage decisions..
3. ***The price, reimbursement, and/or revenue for the product are linked to the outcome of this program of data collection*** either explicitly by a pre-agreed rule or implicitly through an option to renegotiate coverage, price, and revenue at a later date
4. ***The data collection is intended to address uncertainty*** **about ….** ***For example:***
   - efficacy or effectiveness in the tested population as compared to current standard of care;
   - the efficacy or effectiveness in a broader, more heterogeneous population than used in registration trials or in pre-licensing testing;…
5. ***These arrangements provide a different distribution of risk*** between the payer and the manufacturer than the historical manufacturer-payer relationship.

Source: ISPOR PBRSA Task Force Report

Basics: The Pervasiveness of Uncertainty

- Drugs are approved, launched, and reimbursed under conditions of uncertainty, affecting many key parameters:
  - Efficacy (heterogeneity)
  - Effectiveness in real world
  - Risks (safety)
  - Models, including links between surrogate markers and long-term outcomes
  - Cost-effectiveness
  - Budget impact.

1. **Variability→Uncertainty (=Risk)**
2. **Gathering more evidence to reduce uncertainty is costly.**

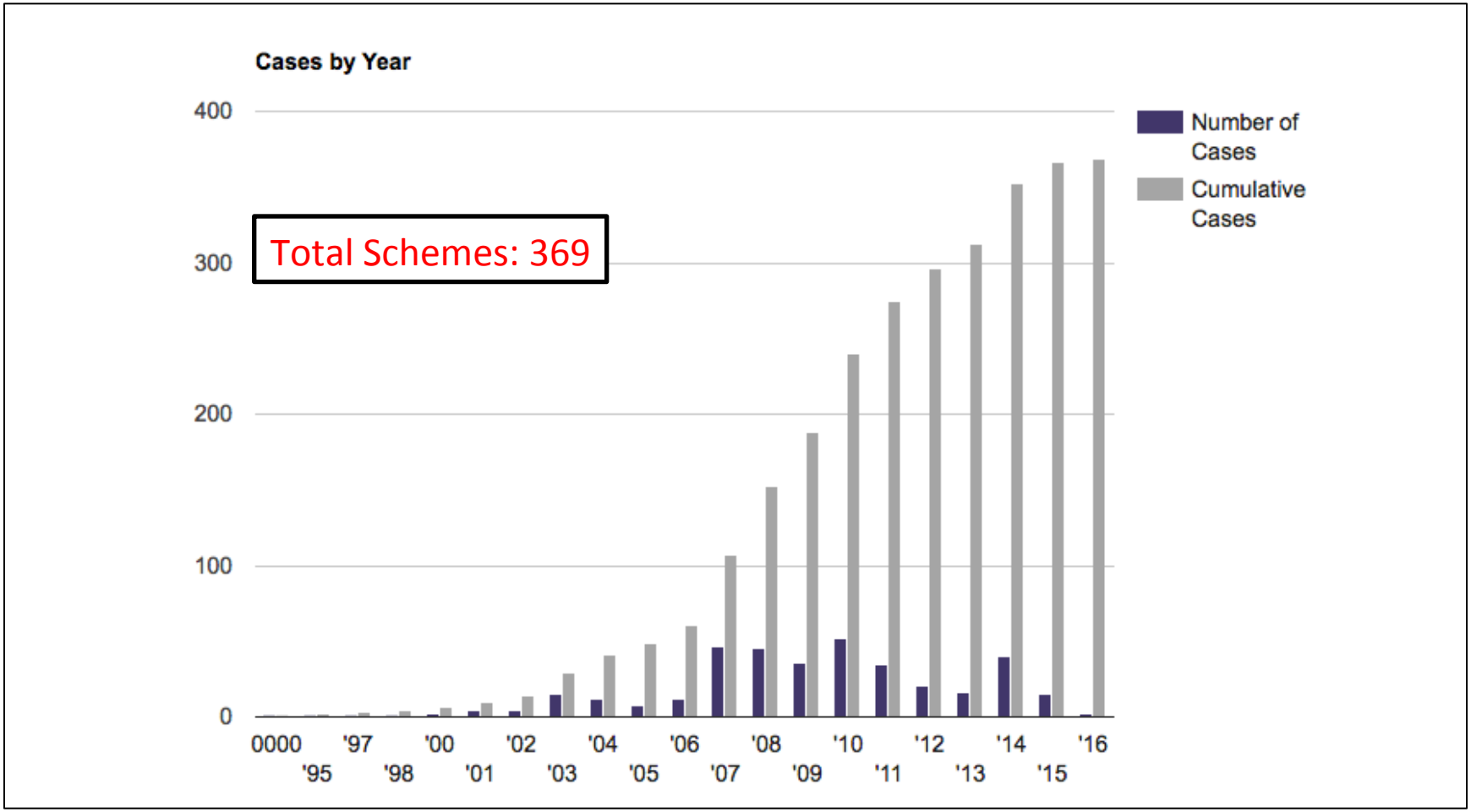
The Historical Risk-Sharing "Equilibrium"

- **Risk to manufacturer:** we operate with a blockbuster financing model for R&D.
  - Intellectual property—patent protection to incentivize investment and risk-taking
  - There is no *ex ante* clause to share innovation cost or to purchase drugs.

- **Risk to payer:** The payer negotiates a price and/or use.
  - The payer—and patient—bear the risks of making a bad buy (i.e., when incremental health benefits are not worth the additional cost).
  - The payer is free to collect post-launch data. Manufacturers will only do this if it is in their competitive interests.

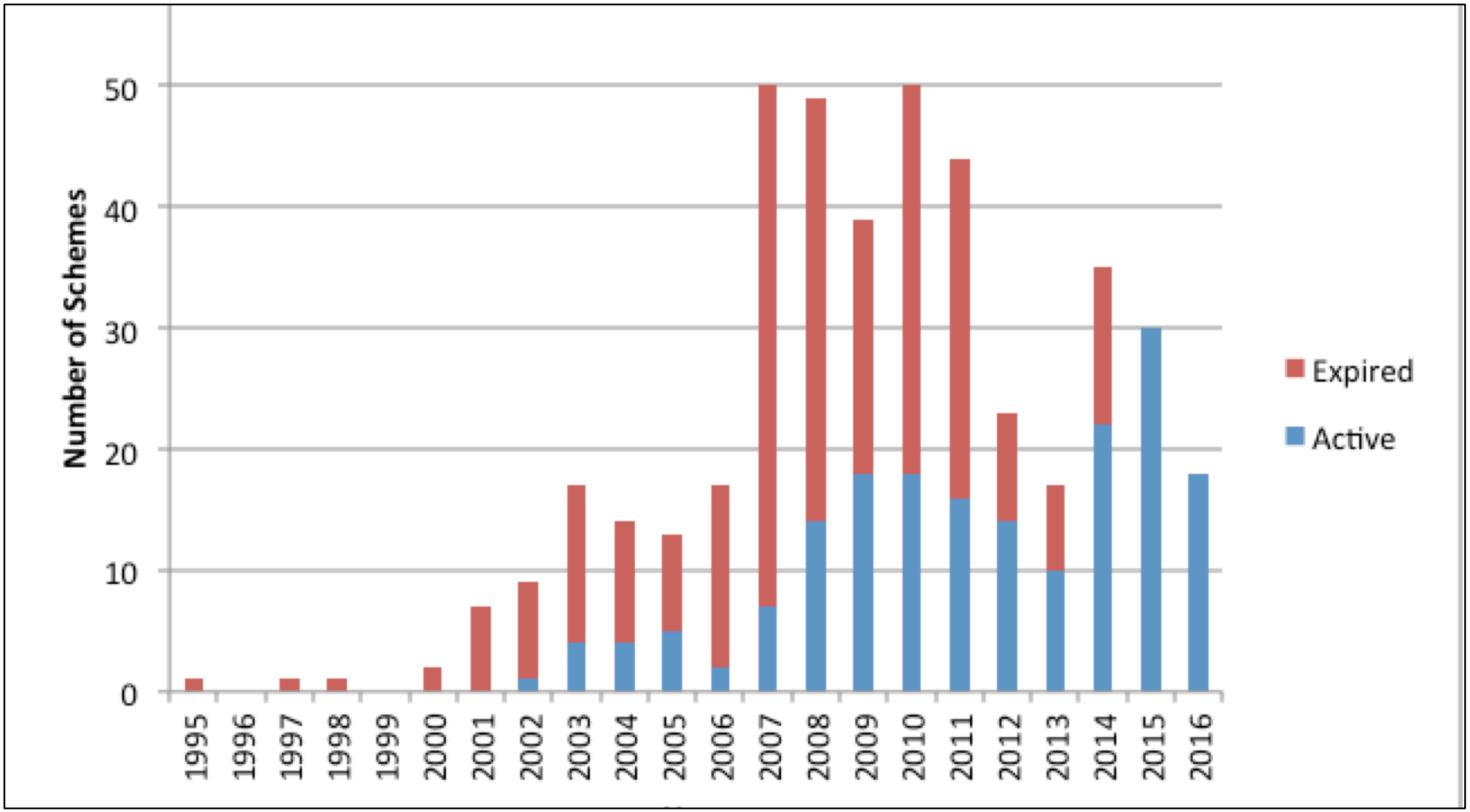
- **Pricing:** Individual countries strike different types of deals with manufacturers
  - Range of country environments: negotiated prices < -- > free pricing
  - All of this provides an incentive for manufacturers to seek highest justifiable price at launch. Manufacturers would like to price for future (larger) indications.

Cumulative and Annual PBRSA Cases by Year



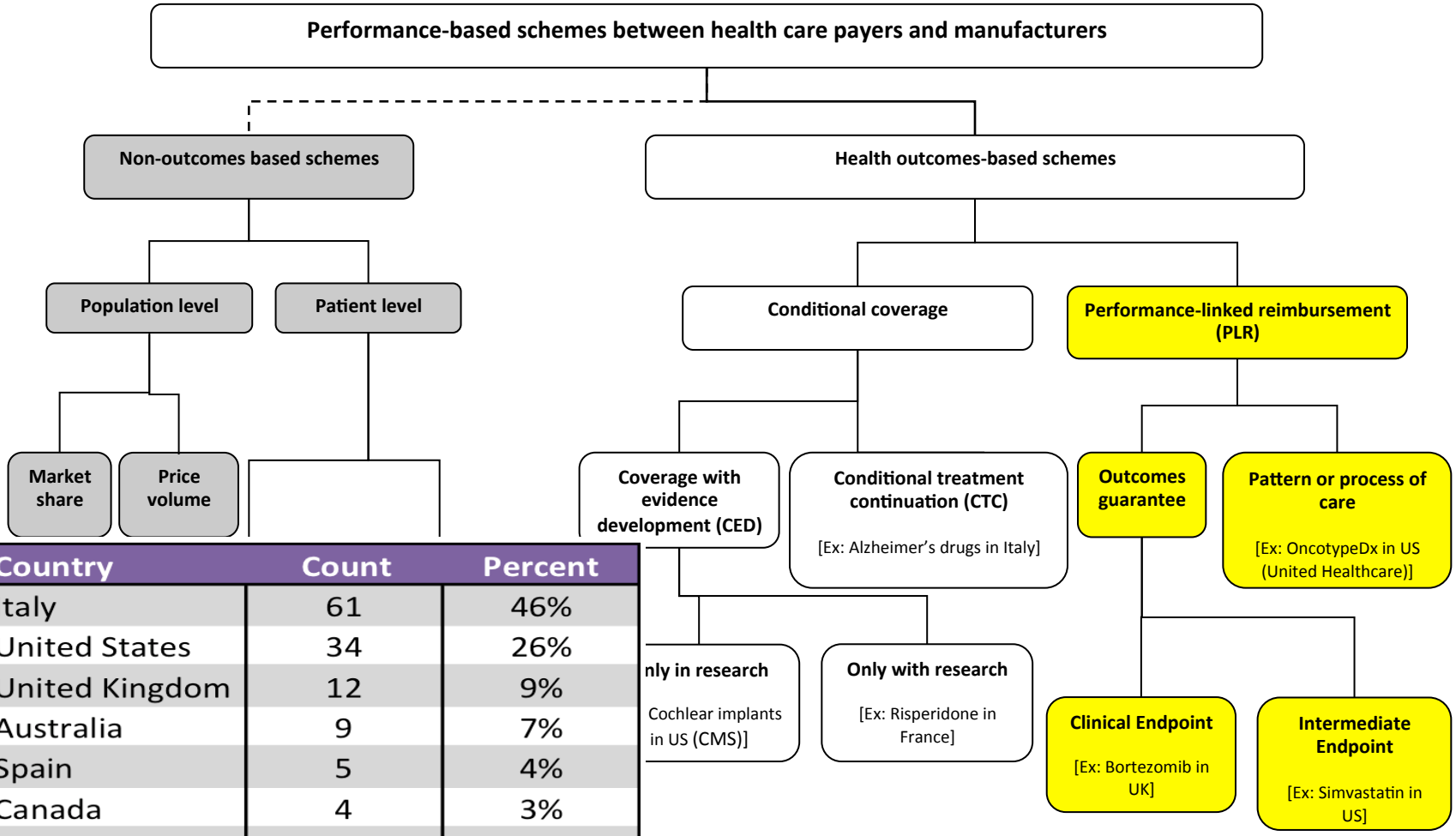
Source: UW PBRSA Database

PBRSA Cases by Year: Active vs. Expired



Source: UW PBRSA Database

UW PBRSA Taxonomy: Performance-Linked Reimbursement



Country	Count	Percent
Italy	61	46%
United States	34	26%
United Kingdom	12	9%
Australia	9	7%
Spain	5	4%
Canada	4	3%
France	2	2%
Slovenia	1	1%
Brazil	1	1%
Germany	4	3%
Total	133	100%

POLICY

Private Sector Risk-Sharing Agreements in the United States: Trends, Barriers, and Prospects

Louis P. Garrison, Jr, PhD; Josh J. Carlson, PhD; Preeti S. Bajaj, PhD; Adrian Towse, MA, MPhil; Peter J. Neumann, ScD; Sean D. Sullivan, PhD; Kimberly Westrich, MA; and Robert W. Dubois, MD, PhD

Key Study Elements:

- Reviewed recent trends in UW database
- In-depth stakeholder interviews
- Online survey on perceptions of future

Key findings:

- Lots of interest and talk by manufacturers
- Substantial implementation barriers
  - Need better data systems
  - Costs of negotiation
- More interest in financially-based RSAs
- Shift incentives? ACOs and government subsidies?

** Source: Garrison et al., AJMC, 2016*

Potential Barriers to PRSAs in U.S.: Interview Results

1. Significant additional effort required to establish / execute RSAs (e.g. compared to traditional rebates / discounts)
2. Challenges in identifying / defining meaningful outcomes
3. Challenges in measuring relevant real-world outcomes
4. Data infrastructure inadequate for measuring / monitoring relevant outcomes
5. Difficulty in reaching contractual agreement (e.g. on the selection of outcomes, patients, data collection methods)
6. Implications for federal best price (Medicaid)
7. Payer concerns about adverse patient selection
8. Fragmented multi-payer insurance market with significant switching among plans
9. Challenges in assessing risk upfront due to uncertainties in real-world performance
10. Lack of control over product use
11. Significant resource and / or costs associated with ongoing adjudication

Source: Garrison et al., "Private Sector RSAs in the United States", September 2015, AJMC, Vols. 21, No. 9

The Question

- From the perspective of academia, what capacity building is necessary to build towards the comprehension and development of RSA in LAC region and how feasible is this?

"Answer":

- Even systems with good health data infrastructure have a difficulty time executing PBRSAs.
- Would require good data analytics, including epidemiology and econometrics to do true outcomes-based agreements
- Need timely and reliable data systems
- Need creative staff with strategic, business-oriented thinking
- Need to fully understand clinical aspects of the treatment: there may be few good candidates or a limited time window for follow-up
- Incentives matter: could we subsidize?

Global Implications

- PBRSAs provide an important opportunity to generate the real-world evidence on product performance that we are sorely lacking.

- The financially-based risk-sharing agreements can provide—via confidential discount—an important avenue for highly desirable differential pricing of medicines across countries with vastly different abilities to pay.

Thanks!
Questions?
lgarrisn@uw.edu