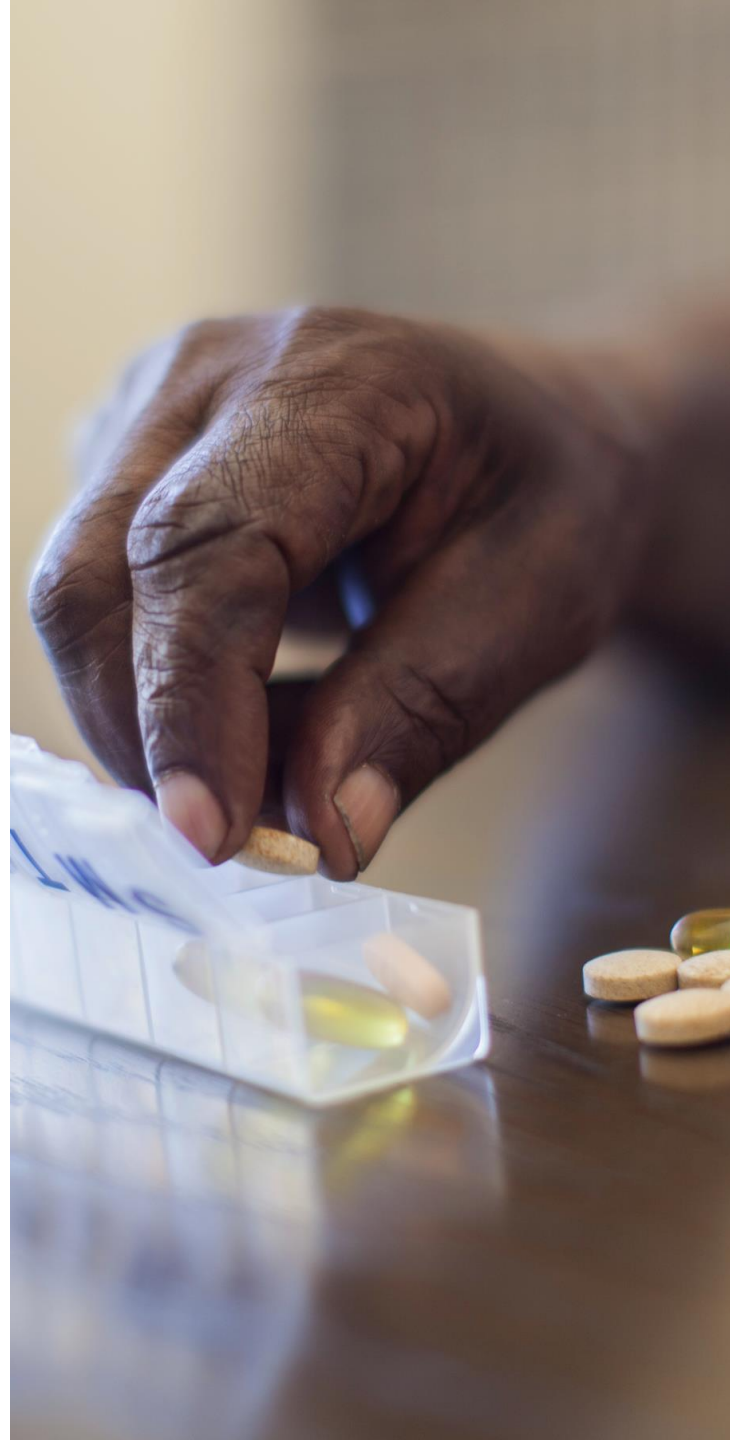


Value-based Pricing: *Considerations for Colombia*

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INSTITUTE FOR CLINICAL
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Outline

- Overview of ICER
- The Growth of Value Frameworks
- ICER's Approach to Assessing Value
- Experience to Date
- Application to the Colombian Context
- Next Steps

About ICER

- Independent non-profit organization with academic history (MGH/Harvard)
- Staff of 20 clinicians, epidemiologists, health economists, and policy researchers
- 70% of funding from private foundations
 - Supports ALL of ICER's project work
- Project process includes multiple opportunities for public engagement and comment
- All of ICER's reports, presentations, and other documents freely and publicly available

The Growth of Value Frameworks

Drug Pricing in the US: The Current Context

FiercePharma

Published on FiercePharma (<http://www.fiercepharma.com>)

Pfizer CEO: Drug-pricing snafu isn't pharma's fault. It's insurers and their poor coverage

October 15, 2015 | By Tracy Staton

Pfizer ([SPFE](#)) CEO [Ian Read](#) says he's met the drug-cost enemy, and it isn't pharma. The firestorm over U.S. drug pricing isn't a problem for drugmakers to solve, Read told *Forbes* in an interview. It's an insurance problem.

The public debate about rising drug prices--be they increases for existing meds or 6-figure cancer-treatment costs--overlooks the financial benefits of drug treatment, Read contends. In his *Forbes* interview, Read cites cost-benefit analyses showing that [Lipitor](#) and other statin meds cost \$305 billion between 1987 and 2008, but they generated \$1.3 trillion in economic benefits, by preventing heart attacks and strokes, and their costs to the healthcare system.

Oncologists' complaints about the rising cost of cancer treatment are similarly misplaced, Read figures. Some high-profile cancer doctors have been vocal about



THIS IMAGE WAS TWEETED BY @MartinShkreli



Pfizer CEO Ian Read

The Need for Value Frameworks

- Growing recognition that value is considered differently depending on stakeholder and perspective
- Some aspects of value can be quantified (e.g., cost-effectiveness)
- Other components are more qualitative in nature (e.g., novelty, innovative approach, better convenience for patients)
- There is interest in capturing these components together in a single framework

Value Frameworks: Many and Varied

- International: NICE, CADTH, IETS, etc.
- General
 - ACC/AHA
 - Premera Blue Cross
 - ICER
- Oncology
 - ASCO
 - Memorial-Sloan Kettering DrugAbacus[®]
 - NCCN

Frameworks Consider Different Attributes of Value

Attribute	ACC/AHA	ASCO	ICER	DrugAbacus	NCCN
Clinical benefit	√	√	√	√	√
Toxicity/safety		√	√	√	√
Cost-effectiveness	√		√		
Affordability			√		√
Treatment novelty			√	√	
Condition rarity				√	

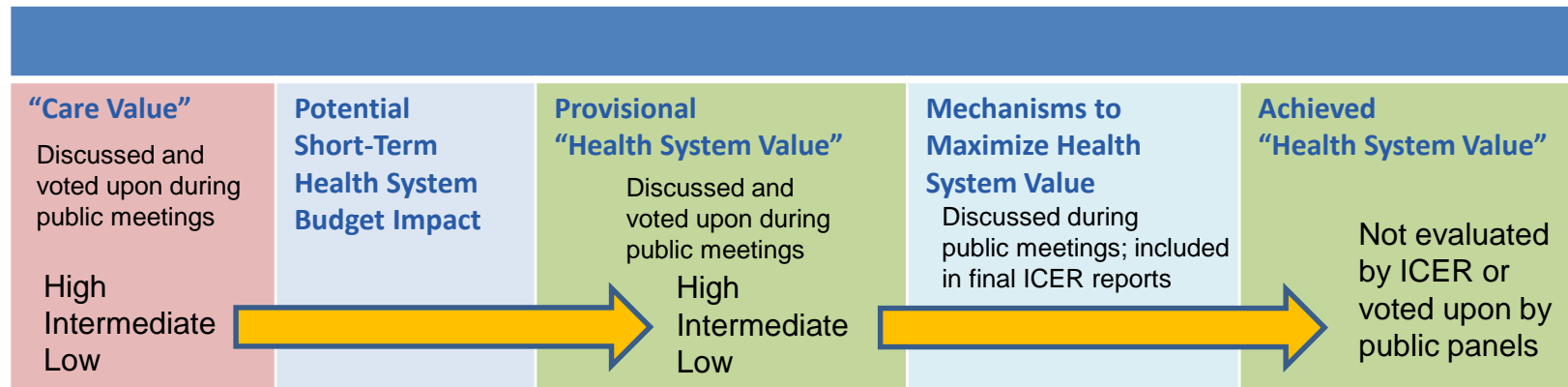
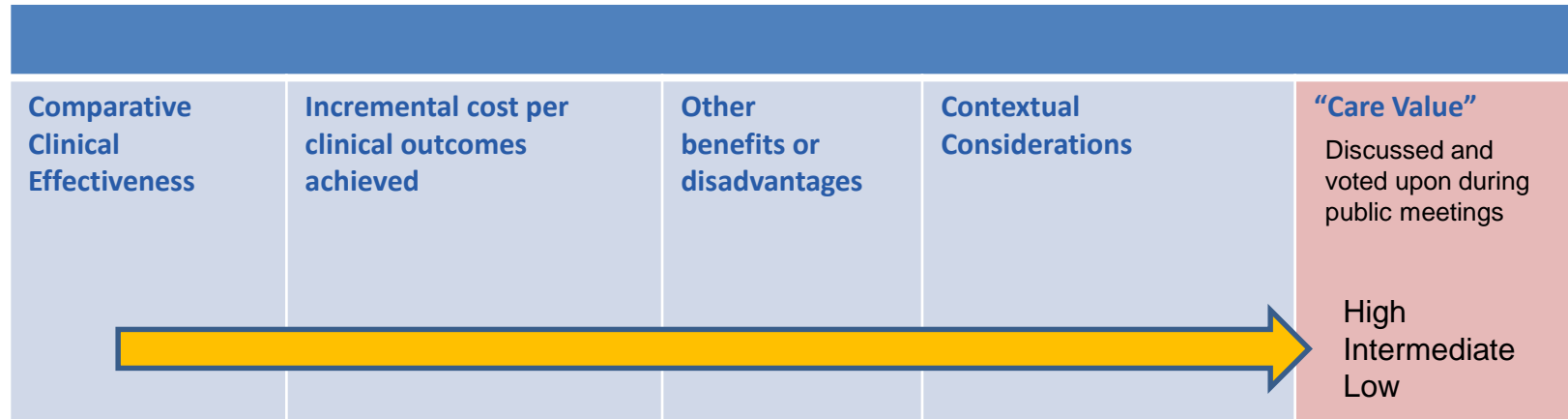
Source: JT Cohen, Tufts Medical Ctr, 2016

ICER's Approach to Assessing Value

ICER's Approach

- The “problems” the value framework was intended to address:
 - Need for improved transparency and consistency of value determinations by HTA groups and payers
 - Mismatch between concepts and terms used to describe value across patients, clinicians, innovators, and payers
 - Need for a more explicit and transparent way for HTA groups and payers to analyze and judge value
 - Framework for population-level policy decisions sensitive to patient and clinician perspectives
 - Addressing potential tension between long-term and short-term perspectives

A Value Assessment Flowchart



Comparative Clinical Effectiveness



- Comparative clinical effectiveness reflects a joint judgment of the magnitude of the comparative net health benefit and the level of certainty in the evidence on net health benefit

Comparative Cost-Effectiveness



- Incremental Cost per Outcomes Achieved
 - ICER uses commonly cited cost/QALY thresholds in its guidance to its public appraisal committees
 - Associated with high care value
 - $< \$100,000/\text{QALY}$
 - Associated with intermediate care value
 - $\$100\text{-}150\text{K}/\text{QALY}$
 - Associated with low care value
 - $> \$150,000/\text{QALY}$

Other Benefits or Disadvantages



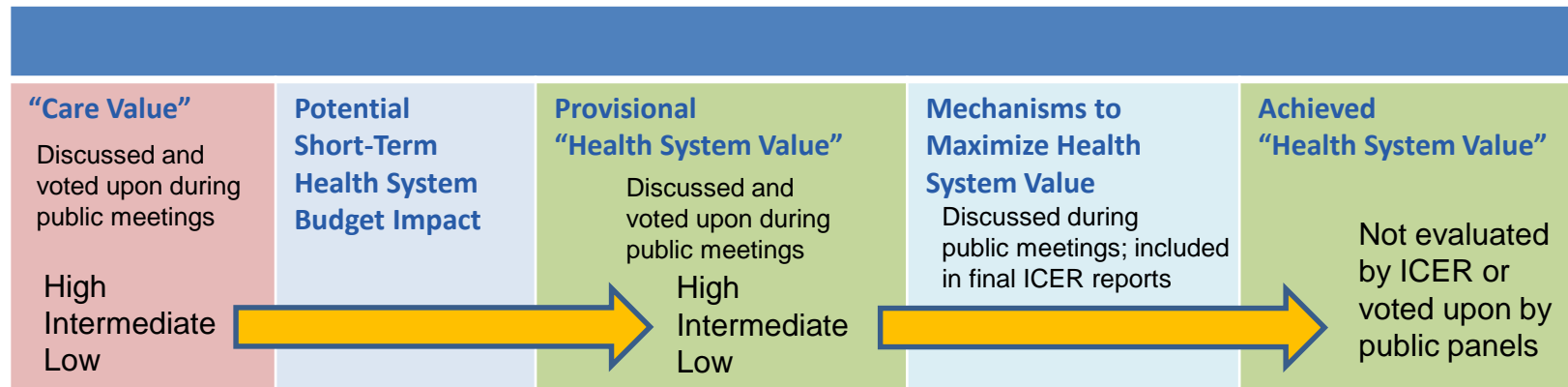
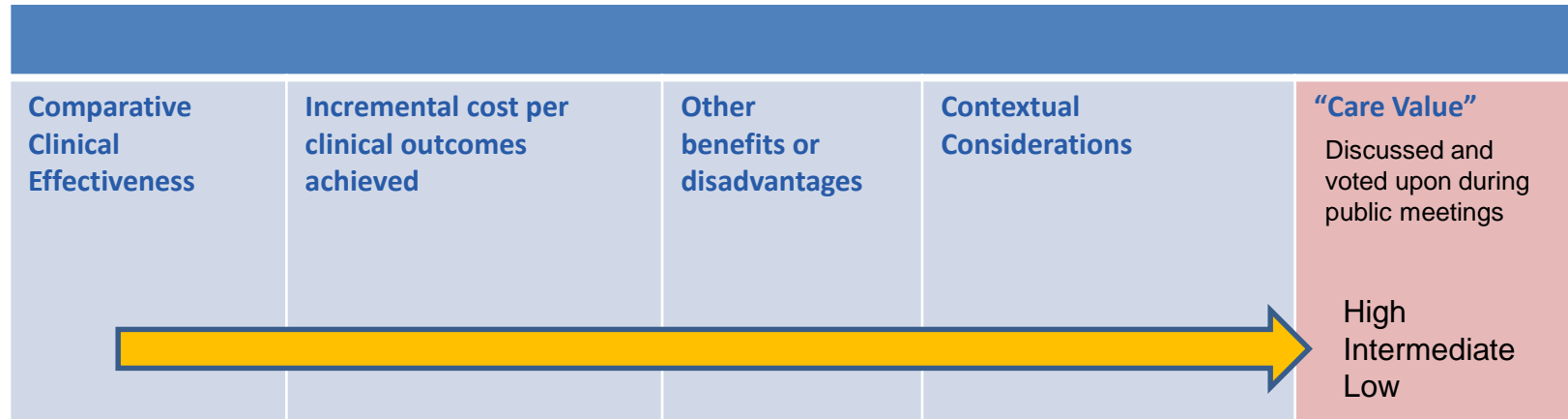
- Other elements of the intervention that are not easily measured
- Examples include:
 - Methods of administration that improve or diminish patient acceptability and adherence
 - A public health benefit, e.g. reducing new infections
 - Treatment outcomes that reduce disparities across various patient groups

Contextual Considerations



- Ethical, legal, or other issues that influence the relative priority of illnesses and interventions
- Examples include:
 - Conditions of extremely high severity
 - Illnesses with no currently acceptable treatments
 - Likelihood of other effective treatments being introduced to practice in near future

A Value Assessment Flowchart



Potential Budgetary Impact



- Need to address tension between long-term value and short-term affordability
- ICER analysis focused on whether treatments with acceptable long-term value may still:
 - Displace other valuable services because of high shorter-term costs (opportunity cost); and/or
 - Lead to unsustainable increases in health care spending

Potential Budgetary Impact (cont'd)




- Threshold is not a “cap” or a tool for drug exclusion
- Simply a signal that steps should be taken to manage affordability
 - Prioritizing treatment
 - Risk-sharing agreements
 - Price reductions

ICER Potential Budget Impact Calculations (2015-2016)

Item	Parameter	Estimate (Drugs)	Estimate (Devices)	Source
1	Growth in US GDP, 2015-2016 (est.) +1%	3.75%	3.75%	World Bank, 2015
2	Total health care spending (\$)	\$3.08 trillion	\$3.08 trillion	CMS NHE, 2014
3	Contribution of drug/device spending to total health care spending (%)	13.3%	6.0%	CMS NHE, Altarum Institute, 2014
4	Contribution of drug spending to total health care spending (\$) (Row 2 x Row 3)	\$410 billion	\$185 billion	Calculation
5	Annual threshold for net health care cost growth for ALL new drugs (Row 1 x Row 4)	\$15.4 billion	\$6.9 billion	Calculation
6	Average annual number of new molecular entity or device approvals, 2013-2014	34	23	FDA, 2014
7	Annual threshold for average cost growth per individual new molecular entity (Row 5 ÷ Row 6)	\$452 million	\$301 million	Calculation
8	Annual threshold for estimated potential budget impact for each individual new molecular entity (doubling of Row 7)	\$904 million	\$603 million	Calculation

Experience to Date: 2 Examples

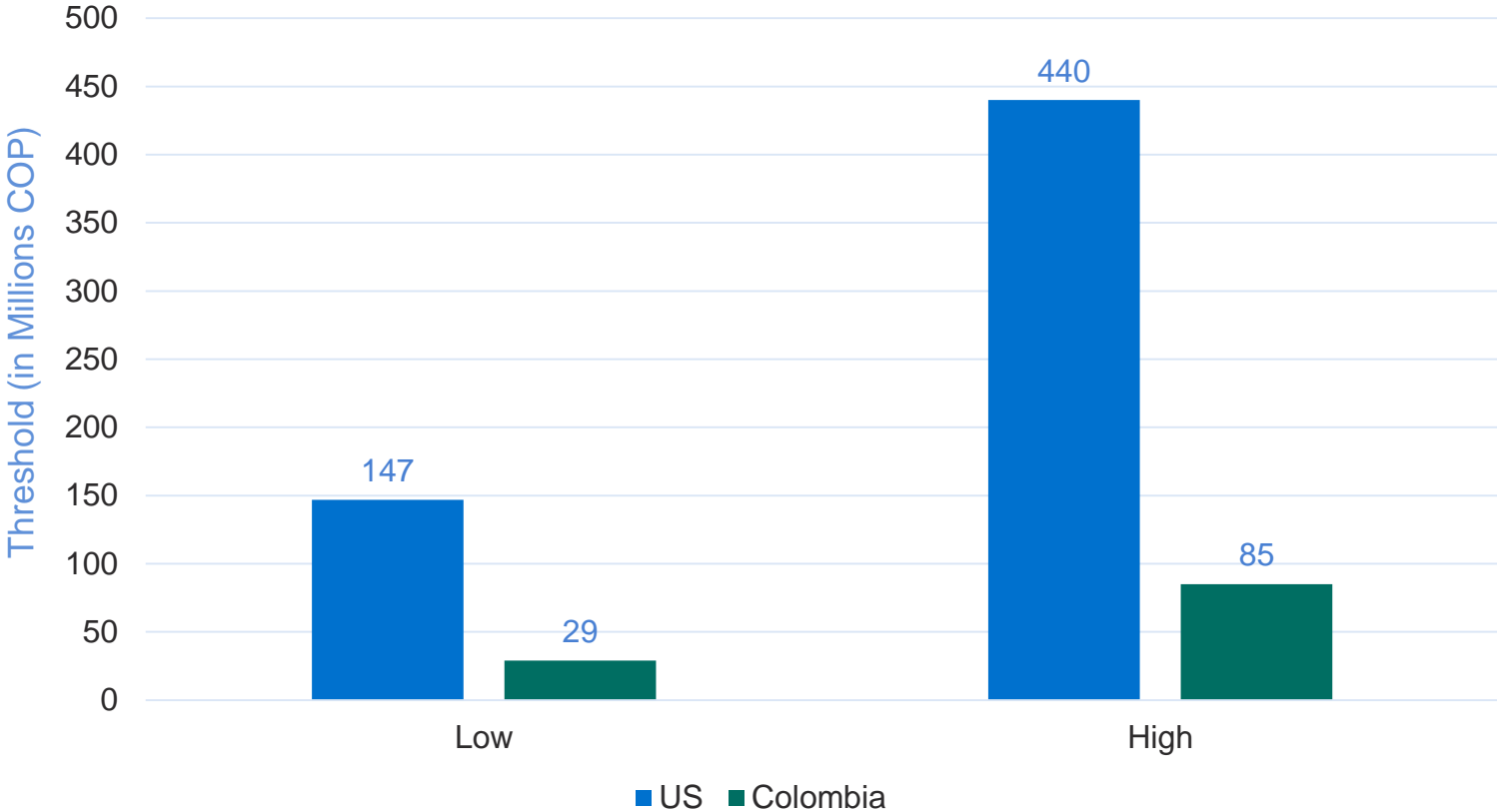
From Value Assessment to Value-Based Price “Benchmarks”

	Price to Achieve \$100K/QALY	Price to Achieve \$150K/QALY	Price at Short-Term Affordability Threshold
PCSK9 Drugs <i>List price \$14,350</i> (n=2,636,179)	\$5,404	\$7,735	\$2,177
	46%-62% discount		

	Price to Achieve \$100K/QALY	Price to Achieve \$150K/QALY	Price at Short-Term Affordability Threshold
Entresto <i>List price \$4,560</i> (n=1,949,400)	\$9,480	\$14,472	\$4,168
	2-3x higher!		9% discount

Application to Colombian Context

Cost-Effectiveness Considerations



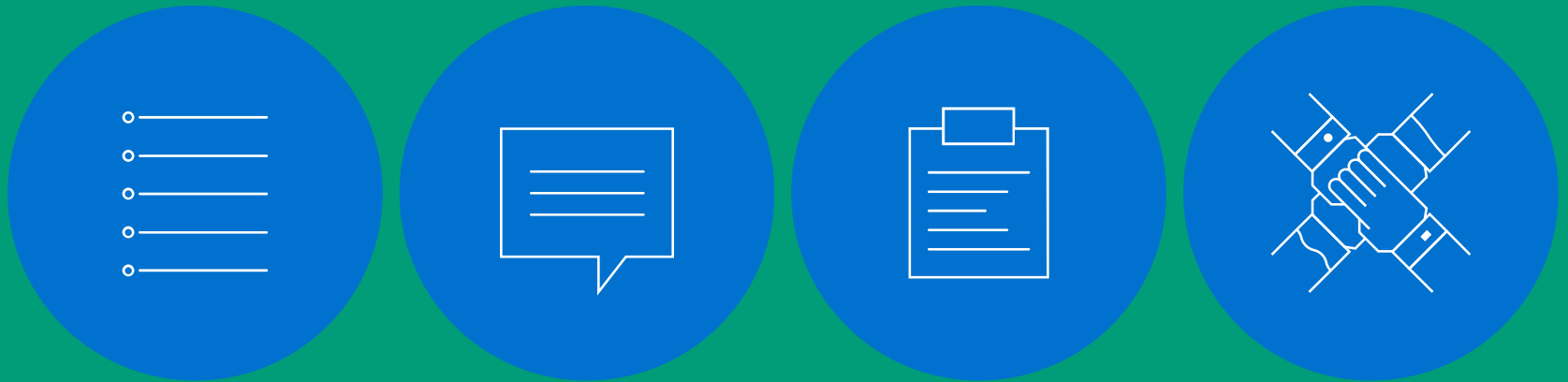
*Based on WHO-CHOICE regional threshold (1-3x GDP)

Budgetary Impact Considerations

- ICER budgetary impact calculation benefits from availability of rigorous data:
 - Total health care spending by sector
 - Percentage of health care spending attributable to pharmaceuticals
 - Number of unique compounds approved by regulators each year
- Availability of similar data in Colombia?
- Question of whether GDP growth is an appropriate measure vs. tax revenues?

Other Concerns

- There are challenges in the US in applying the ICER framework to decision-making:
 - Marketing authorization occurs at time of regulatory approval
 - List price is typically set before our reviews are complete
 - There are no laws requiring manufacturers to submit any data to ICER
- In nearly all other countries HTA/pricing decisions are made **BEFORE** marketing authorization



Next Steps

Next Steps

- ICER has issued an open call for comments on its value framework
- The framework will be discussed at a multi-stakeholder meeting in Washington, DC (September)
- Any necessary revisions will be made by January 2017

Questions?

www.icer-review.org

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