Value-Based Pricing of Pharmaceuticals in the US:

Emerging Reality or Pipe Dream?

ICER
INSTITUTE FOR CLINICAL AND ECONOMIC REVIEW

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- I have no other conflicts to disclose.

Outline

- What is ICER?
- Context
- What is Value-based Pricing?
- The International Experience
- US-based Value Frameworks
- ICER's experience
- Q&A

Institute for Clinical and Economic Review (ICER)

- **Independent** health technology assessment group with academic roots

- Develop **publicly available assessment reports**
  - Drugs
  - Devices/procedures
  - Health system interventions

- Convene regional independent **appraisal committees** for public hearings on each report

- The **“national drug cost watchdog”**

ICER's Raison D'Etre

- *"When one party in a deal knows more about the goods than the other, economists call it information asymmetry. It's a classic recipe for market failure and, as any seasoned negotiator knows, a great way to get a bad deal."*
- *"Pearson, with ICER, has taken it upon himself to fix this information imbalance, to generate the missing data and calculate a "fair price" for drugs. It is straightforward yet radical work – a missing puzzle piece in the effort to solve our drug-pricing crisis."*

  -- Wired magazine, 6-10-17

Independent Appraisal Committees

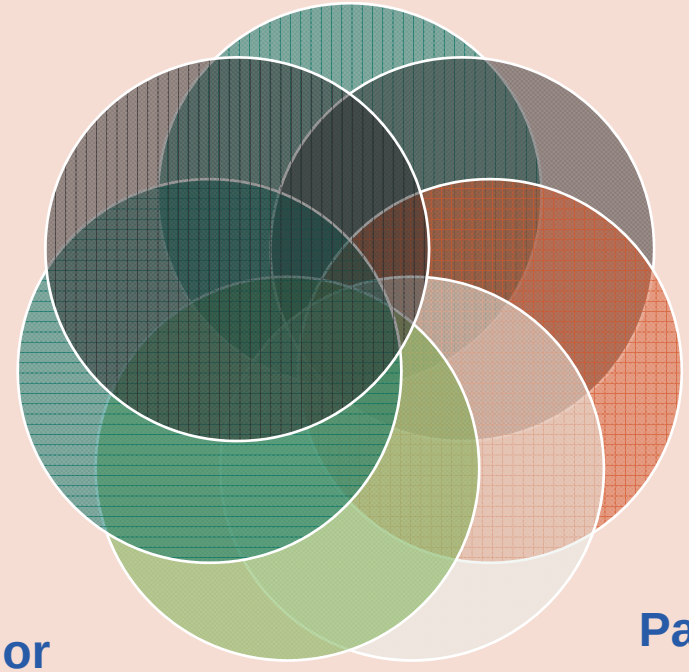
Our Current Context/Intro to Value-based Pricing

How Did We Get Here?

Innovative pipeline and maximal generic prescribing

Prescribers disconnected from cost concerns

Market exclusivity = protected monopoly for brand drugs



Private payer negotiating power is limited

Patent extension and other ways to limit competition

No federal negotiation or regulation of prices

Payers and consumers lack credible information on effectiveness and value

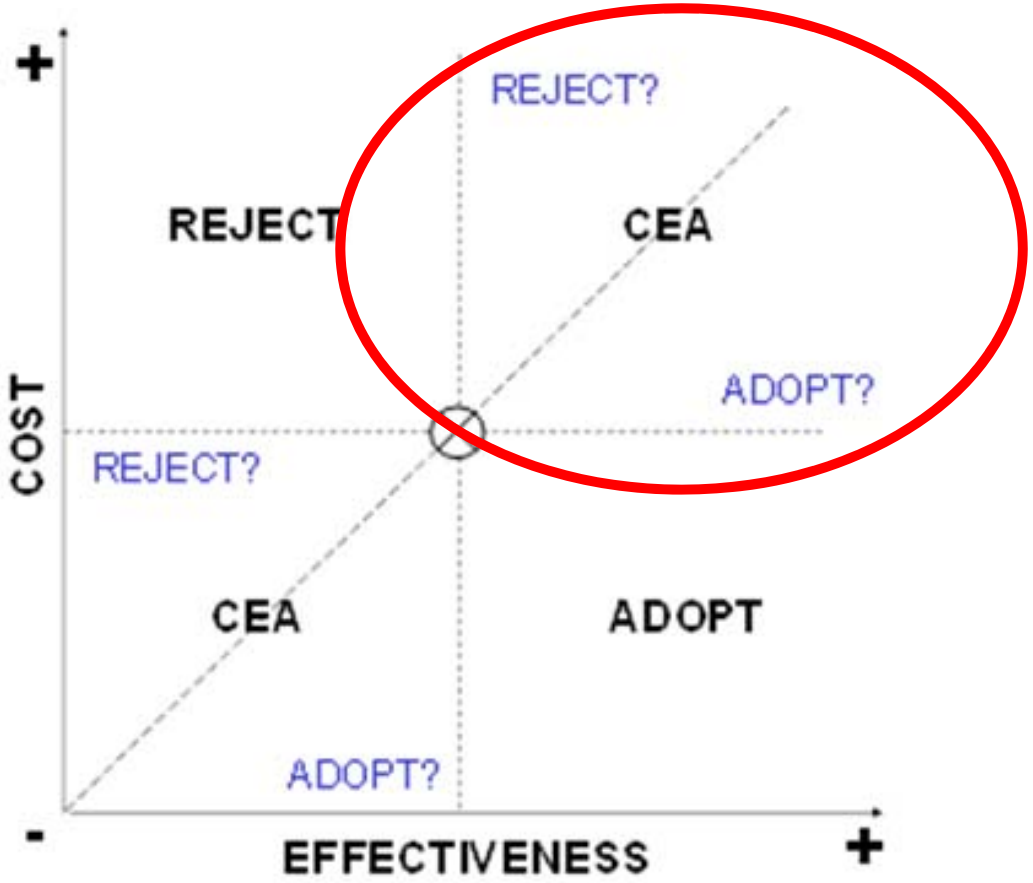
What is Value-based Pricing?

- Relationship of price of goods to their value or utility is nothing new
- 18th century "classical economics" focused on utility to society or distinct societal class
  - E.g., Smith, Malthus
- Utility to the individual has been discussed for millennia, dating back to ancient Greeks (e.g., Epicurus)
- Formal school of thought first proposed by Bentham in early 1800s

What is Value-based Pricing? Cost-Effectiveness in Health

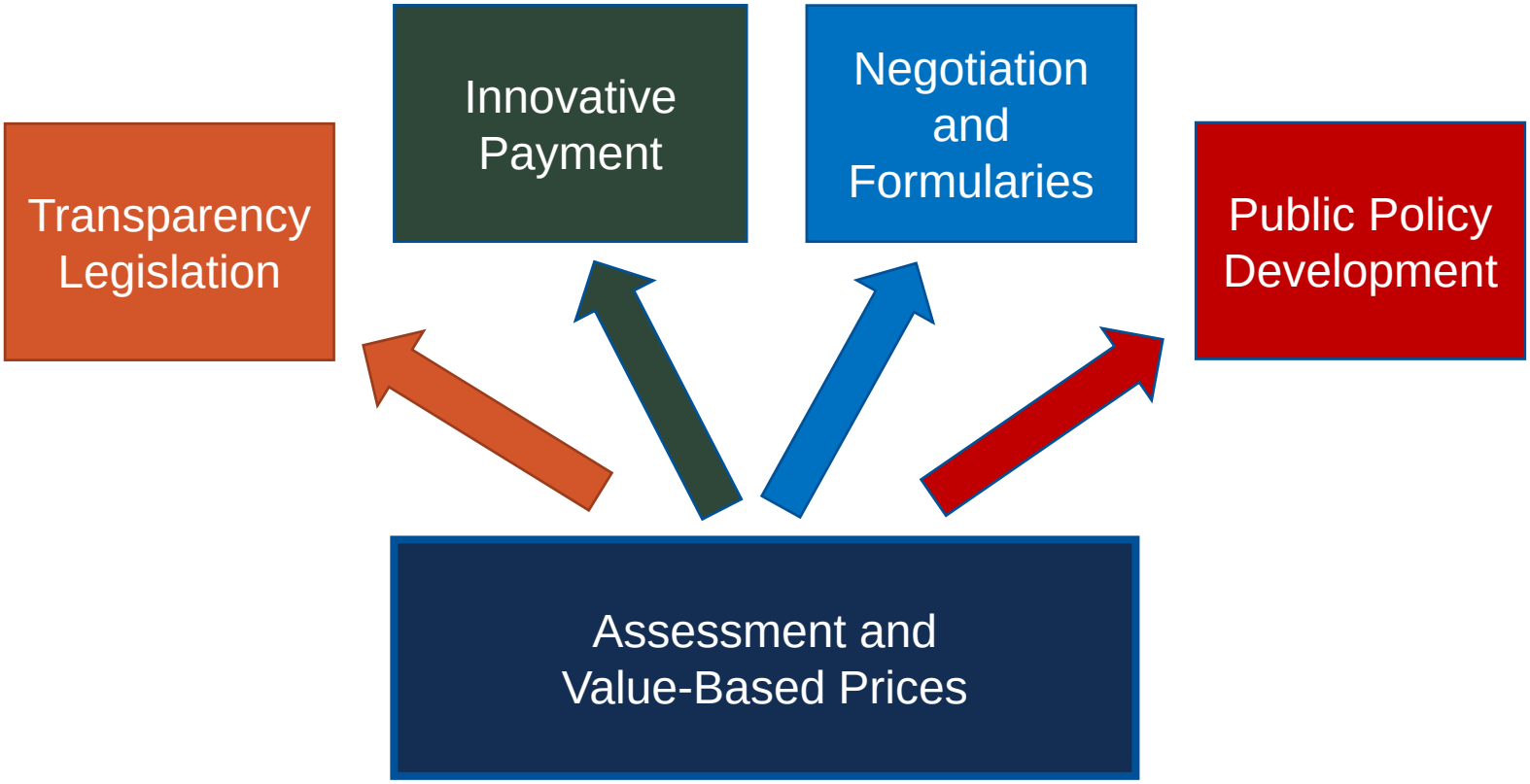
- Formalized cost-effectiveness analysis developed in 1960s to assist with resource allocation in the military
- Weinstein and Stason (1977) published landmark NEJM paper adapting cost-effectiveness to healthcare settings:
  - *Ratio of net costs to net benefits*
  - *Utility weights to adjust life expectancy for quality of life*
  - *Discounting of future costs and benefits*
  - *Sensitivity analyses to address model uncertainty*

Interpreting Cost-Effectiveness Findings



Source: Goodman C. HTA 101: Introduction to Health Technology Assessment. https://www.nlm.nih.gov/nichsr/hta101/ta10101.html

The central role of value assessment



Does Value Drive Decisions in the US?

Intervention	Cost per QALY Gained	Medicare Usage Rates
Colon-cancer screening	$10,000 - $25,000	20-35%
Secondary prevention of high cholesterol	Cost-saving - $50,000	30%
Anti-hypertensives	$10,000 - $60,000	35%
Lung volume reduction	$150,000 - $300,000	20,000 cases/yr
Left ventricular assist devices	$500,000 - $1.4 million	100,000 cases/yr

Source: Neumann PJ et al. NEJM 2005;353:1516-22

Does Value Drive Decisions in the US?

- Office of Technology Assessment (OTA)
  - Funded in 1972
  - Unique model with governing board balanced both politically and with special interest input
  - Held up as an international example of robust science and methods (used CEA across industries)
  - Died a slow death after questioning scientific and economic feasibility of Strategic Defense Initiative
  - De-funded in 1995

The International Experience

Embedding Value in HTA Processes

- Health technology assessment (HTA) as a discipline has also been around since the 1960s
- Natural outgrowth of growing need to keep pace with technological innovation in health and other disciplines
- HTA exists in every developed nation in form of government agencies or other authority receiving appropriations:
  - *Any current US-based acronyms come to mind?*

Embedding Value in HTA Processes

- Evolution of approach to considering value hit its stride in mid-to-late 1990s
- Conversion of Canadian provincial HTA to pan-Canadian effort (CADTH), creation of NICE, expansion of Australian PBAC and MSAC, etc.
- Typical process involves manufacturer submission of systematic review and country-specific economic model for evaluation by authority and academic collaborators

What is “Good” Value in International HTA?

- Varies by country/authority
- NICE: £20,000 - £30,000 per QALY
- Single thresholds in Spain, New Zealand, Ireland
  - Range: €20,000 - €45,000 per QALY
- Thresholds dynamic in Canada/Australia
- *Operationalizing “value” increasingly tied to questions of affordability*

US-based Value Frameworks

Growth in Value Frameworks: Why?

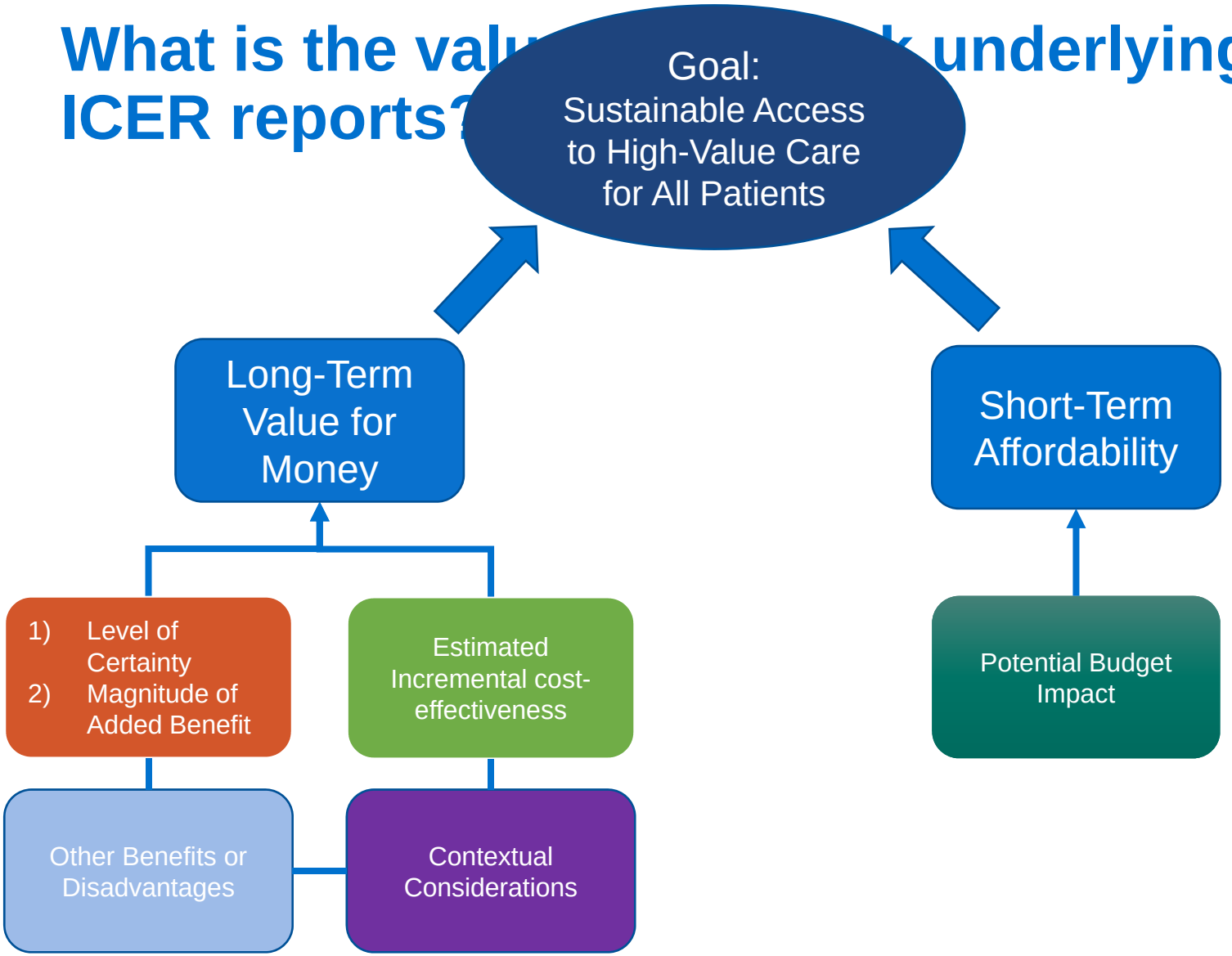
- Even in nations with mature HTA processes, concern with narrow focus on cost-effectiveness as primary determinant of value
- Patient groups: *some aspects critically important to us are essentially impossible to quantify*
- Industry: *it's not just value as an endgame, it must preserve incentives to innovate*
- Clinicians: *we still have no idea how to talk about this stuff with our patients*

Newer Frameworks: Different Attributes, Different Audiences

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

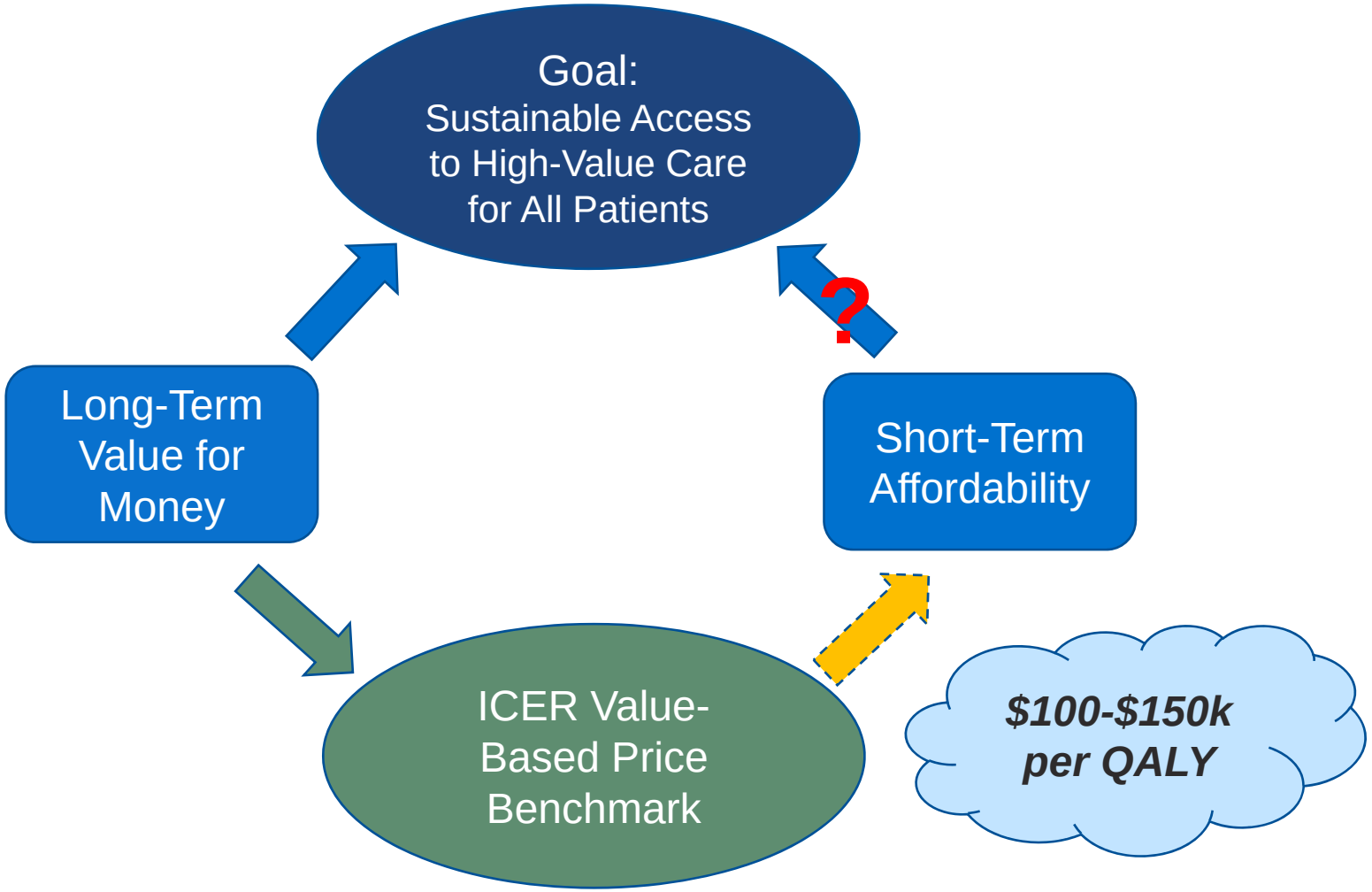
What is the valu[illegible]k underlying ICER reports?



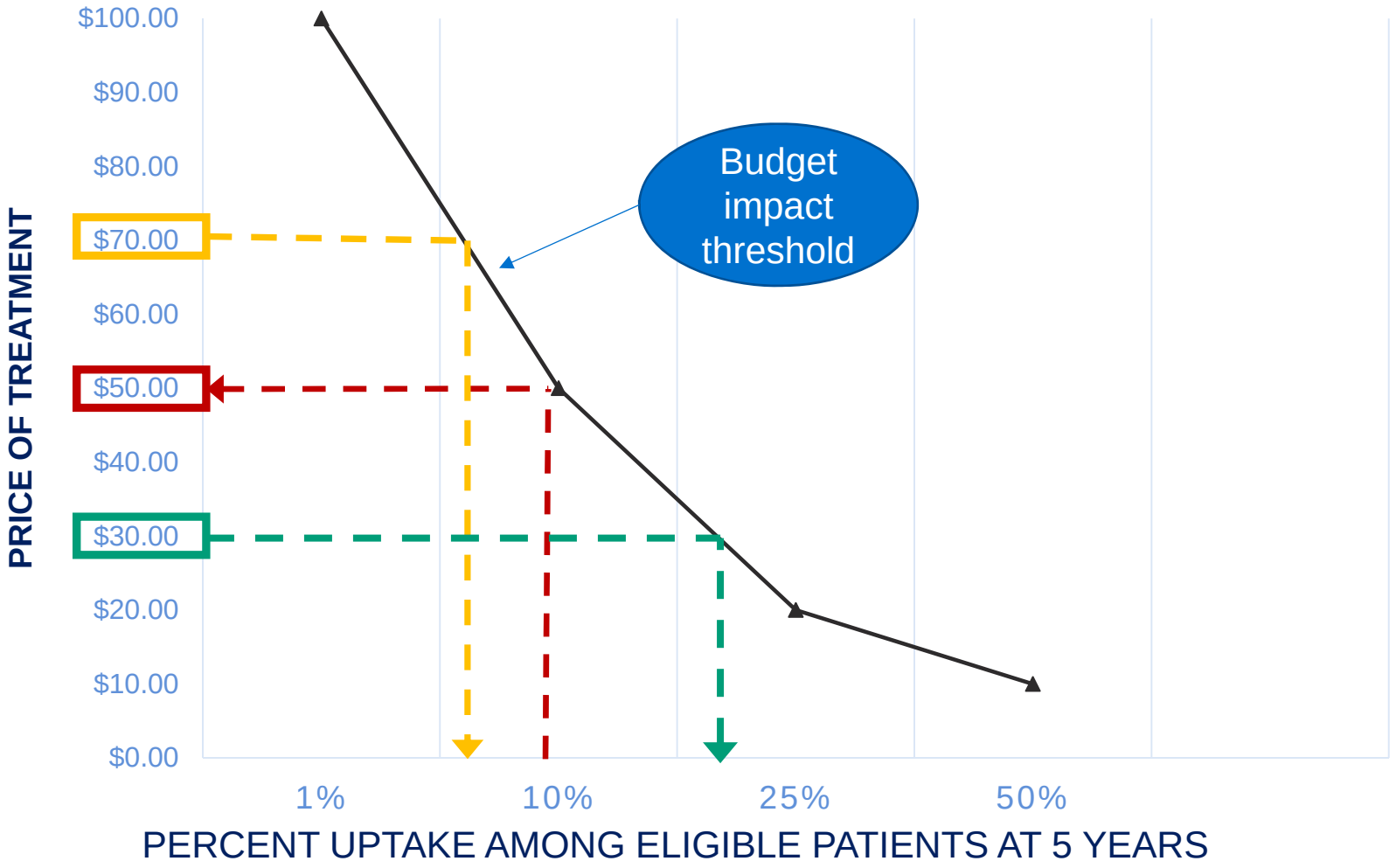
Factors Affecting Long-Term Value for Money

- Condition-specific
  - Disease severity
  - Burden of illness/"QALY shortfall"
  - Effectiveness of current standard of care
  - Near-term horizon for other innovations
  - Other ethical/legal/social concerns
- Intervention-specific
  - Treatment simplicity/complexity
  - Benefit of new mechanism of action
  - Impact on productivity/caregiver burden
  - Uncertainty, especially on long-term safety
  - Other unmeasured patient benefits

ICER value-based price benchmark



POTENTIAL BUDGET IMPACT SCENARIOS

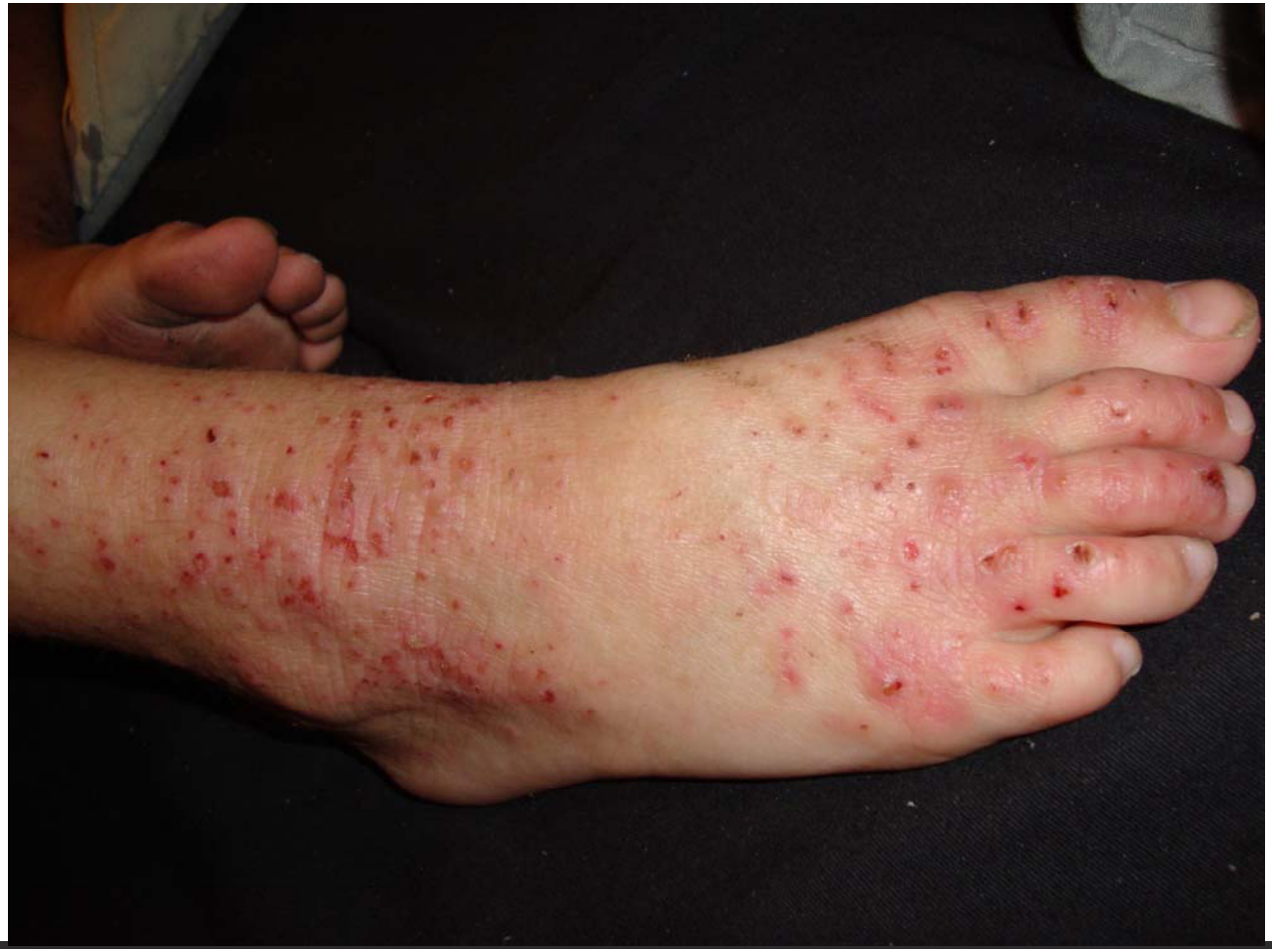


ICER's Experience: Are Prices Becoming Value-based?

ICER Reports and Value-based Pricing

Drug category	Approximate Discount to Meet Value-based Price Range	Short Term Affordability/Access Alert?
High cholesterol	50%	Yes

Severe Atopic Dermatitis and Dupilumab



Dupilumab: What was Expected

- First biologic for patients with great unmet need
- Significant clinician interest
- No competitor on the near-term horizon
- Launch price c/w price for psoriasis drugs: $60K
- 350,000 – 400,000 million eligible patients
- Anticipated payer reaction:
  - Grudging acquiescence to manufacturer price
  - Stiff coverage prior authorization to limit use
  - Increase in future premiums and cost-sharing
- 200,000 patients get the drug at cost of $12B

Dupilumab: What Actually Happened

- *Regeneron said [to ICER] that it wanted to hit the lower end of ICER's rating – to come in at the 'high value' end of the scoring – and wanted to be able to tell pharmacy benefits managers this during negotiations. …the company announced that…with some negotiated rebates, [the drug] would come in at around $31,000 – right at the golden end of ICER's scale. 'Pretty damned responsible,' in [Regeneron CEO Len Shleifer's] words."*

  -- Wired magazine, 6-10-17

- *"I'd characterize it as a responsible price," says Steven Miller, chief medical officer at Express Scripts Holding Co., the largest PBM. "Neither side got everything it wanted, but this has been responsible."*

  -- Wall Street Journal, 3-28-17

Was Dupilumab a “One-Off”?

- Something of a trend: launch prices trailing market expectations
  - MS: Ocrelizumab
  - Psoriasis: Brodalumab
  - RA: Sarilumab
- But should not be confused with value-based pricing!
- What is needed: pricing that is in clear alignment with benefit to patients

Is Outcomes-based Contracting the Answer?

- NO
- Does not on its own serve to bring price and benefit to patient into alignment
- Can be used to cement value proposition (sacubitril/valsartan)
- Cannot be used as substitute when price out of alignment with benefit (PCSK9i)

Q&A