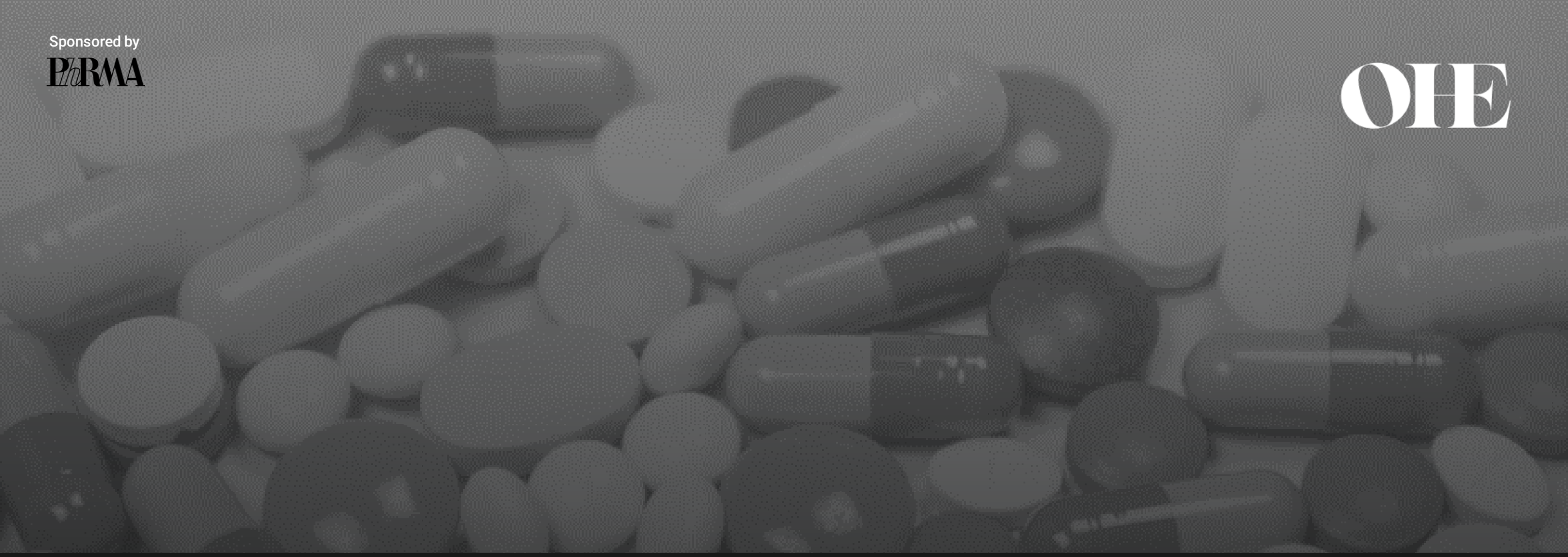

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ISPOR ISSUE PANEL
8TH MAY 2023

Considering the Impact of the Inflation Reduction Act on Drug Development and Patients

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Agenda

AGENDA	
Welcome and Introduction	Prof Lotte Steuten
Investor's perspective on drug development incentives and innovation	Dr Ravi Mehrotra
Patient's perspective on access to emerging therapeutics for older adult populations.	Michael Ward
Value assessment perspective on balancing equitable patient access and financial sustainability	Dr Jason Spangler
Audience Q & A	All
Closing Remarks	Prof Lotte Steuten

Welcome and Introduction

Prof Lotte Steuten, Deputy Chief Executive, OHE

Overview of drug pricing provisions in the Inflation Reduction Act

Price setting

Beginning in 2026, HHS will set Medicare prices for eligible prescription medicines in Part D. In 2028, this will be expanded to include eligible medicines in Part B.

Inflation Rebates

IRA introduces an inflation rebate to quarterly (Part B) and annual (Part D) price increases above inflation.

Part D Redesign and other provisions

Changes stakeholder liability for drug costs, caps out-of-pocket spending, smooths cost sharing, and makes other changes to benefits.

Under the IRA, federal government will set prices for selected drugs covered under Medicare

Before the Inflation Reduction Act (IRA)

- Part D was a market-based system with drug prices privately negotiated
- Direct government involvement in pricing prohibited by the **non-interference clause** in Medicare Part D.
- Payment for physician-administered drugs covered by Medicare Part B generally based on Average Sales Price (ASP) + 6%

Now

- IRA introduces provisions for the Secretary of the Department of Health and Human Services (HHS) to set Medicare prices for certain eligible medicines
- The Centers for Medicare & Medicaid Services (CMS), an operating division of HHS, will implement the drug pricing provisions of the IRA.

MEDICARE DRUG PRICE NEGOTIATION PROGRAM
CENTERS FOR MEDICARE & MEDICAID SERVICES

What drugs are eligible for selection?

Eligible for selection

Drugs with the highest total Medicare Part B & D expenditures*

Top 50 eligible drugs in **Part B**, ranked by program expenditures	+	Top 50 eligible drugs in **Part D**, ranked by program expenditures

- ✓ Single-source drugs**, 7 or more years after FDA approval
- ✓ Single-source biologics**, 11 or more years after FDA approval

* For years 2026 and 2027, only the top 50 Part D list is used

Ineligible for selection

- ⊗ Drugs with a single orphan designation that are only approved for that indication(s)*
- ⊗ Plasma-derived products
- ⊗ "Low spend Medicare drugs" (total Part B & Part D expend <$200 mill annually)
- ⊗ Certain "small biotech drugs" up until 2028

*Under CMS' guidance, risk that as soon as the sponsor has an additional designation or any additional indication (whether under a subsequent orphan designation or not) they are no longer ineligible

Initial CMS guidance

***A "Qualifying single source drug" includes all dosage forms and strengths with the same active moiety (for small molecule drugs) or active ingredient (for biologics). Note: If any dosage form/strength of a single source drug or biologic is on the market for 7 or 11 years, respectively , then all dosage forms/strengths of the drug will be considered for "negotiation."*

Manufacturer is subject to penalties for refusing to participate or not accepting MFP; other penalties could apply

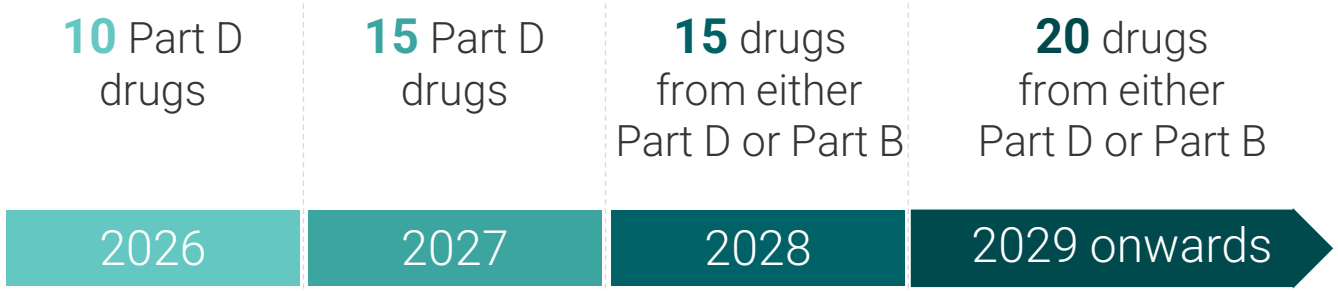
Excise tax is nominally between 65% and 95% of manufacturer's total sales for the drug, over the term in which manufacturer fails to accept MFP.

Alternatively, manufacturer can exit program~~s~~ but must remove all of its drugs from Medicare and Medicaid.

Significant civil monetary penalties for failing to comply with certain requirements or knowingly submitting false information

There will be a gradual rollout, in which more drugs will be selected for price setting each and every year

- Beginning in 2026, CMS will set Medicare prices for eligible prescription drugs



- Selection of drugs each year is cumulative, adding to the number of previously selected drugs.

Process for determining the maximum fair price

IRA specifies 2 sets of factors that HHS should consider in determining the *maximum fair* price.

Manufacturer-Specific Data

- R&D Costs and Extent of Recoupment
- Unit Costs of Production / Distribution
- Prior Federal Financial Support
- Patent Applications, Exclusivity Data and FDA Applications / Approvals
- Market Data, Revenue and Sales Volume Data

Clinical Benefit Compared to "Therapeutic Alternatives"

- "Therapeutic Advance" / Costs of Alternatives
- Prescribing information of drug and alternatives
- Comparative effectiveness of drug and its alternatives
- Unmet medical need

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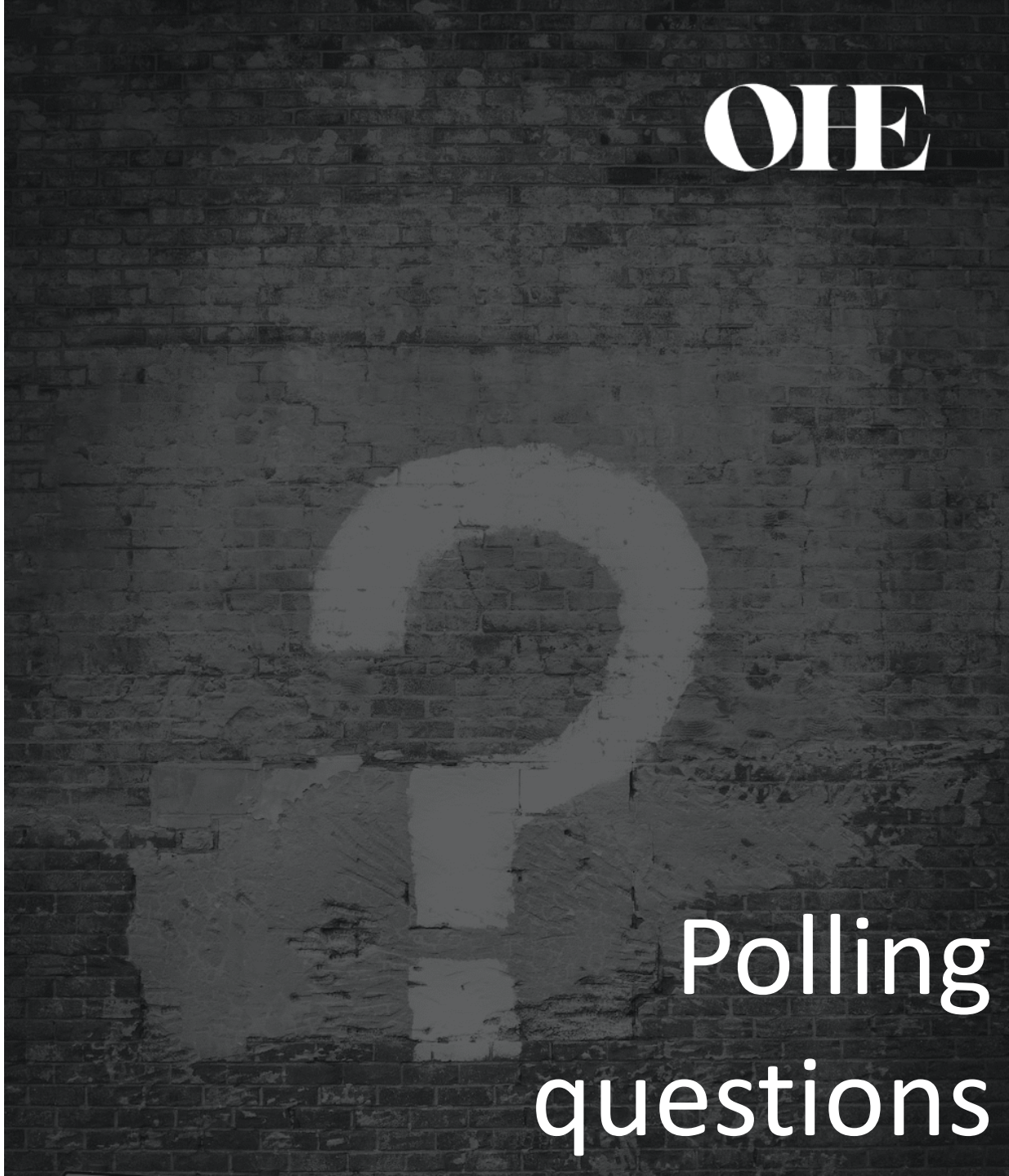
You can find out more on OHE's dedicated platform

https://www.ohecourseinflationreductionact.com/

Impact on drug development and patients?
Questions arising

- R&D costs and incentives for manufacturers?
- Post-approval R&D strategies related to new therapeutic uses of a medicine?
- Distortionary R&D effects on certain types of patient populations or disease areas, including rare diseases?
- Impacts on incentives for generic and biosimilar entry?
- Lessons from government price regulatory schemes elsewhere?
- Impact on timing and countries for launching new medicines or indications over time?
- Impact on plan formularies and competitive dynamics? And downstream drug development within a therapeutic class?

But first, some questions for you



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CONSIDERING THE IMPACT OF THE INFLATION REDUCTION ACT ON DRUG DEVELOPMENT AND PATIENTS

An Investors Prospective

AN INVESTOR'S PROSPECTIVE

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(1) Institutional Investors' view on IRA constantly evolving – **becoming bigger/major focus**

(2) Will there be continued **change** to the act or is this "it"

(3) What is the **real world $ impact** of the act to the industry? **[Exhibit 1]**

(4) Which companies / therapeutic areas / modalities does it **impact the most**?

(5) What are the likely **structural changes** within the totality of the biopharma industry? **[Exhibit 2]**

(6) Will it ultimately **change R&D investment approach** in the biopharma industry – does its impact **"innovation"? [Exhibit 3]**

The question rarely asked -

Has it solved "the problem?"

EXHIBIT 1: THE REAL WORLD $ IMPACT OF THE ACT TO THE INDUSTRY?

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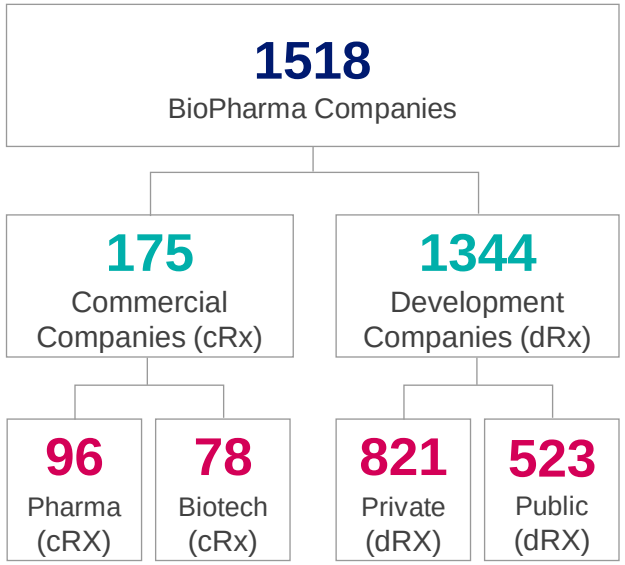
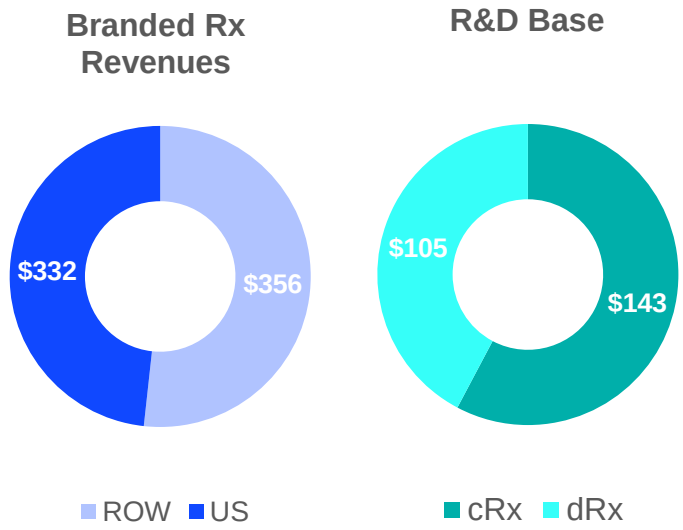
WBPI = Consolidation of the Branded Drugs Industry

World BioPharma Inc. (WBPI) is a single, hypothetical entity which consolidates all the companies that discover, develop, and commercialize the totality of the branded prescription drugs industry



WBPI Key Numbers



WBPI 2019 P&L Statement

Worldwide Net Revenues	687,447
COGS	175,566
R&D	247,505
SG&A	188,919
Operating Income	**75,456**

(all numbers in $US millions)

The Impact of the IRA

~20% of operating income of WBPI using "mid-point" CBO estimate of ~$160B over year years or about $15B/year

Real world impact could be bigger than 20% (1) US disproportionality contributes to WBPI operating profit (2) IRA impact will roll over into commercial plan pricing (3) IRA hits "tail" revenues where profit margins are higher

R&D budgets will inevitably be hit, key questions are "how much" and "where"?

EXHIBIT 1 PART 2: THE COMPARISON OF R&D, SGA AND OPERATING INCOME OF WBPI VS OTHER SECTORS

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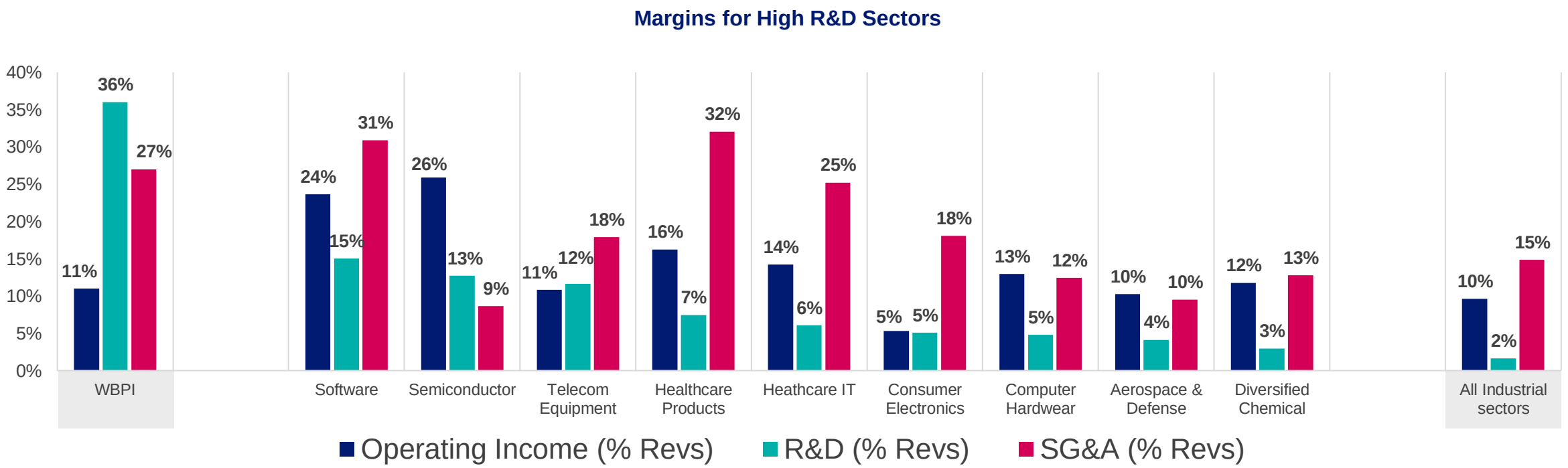
WBPI has the highest R&D cost of all sectors, yet an operating income in line with the general market.



CONCLUSION : A >20% hit to operating income for the biopharma industry is BIG – there WILL BE CHANGES to the industry

EXHIBIT 2: THE STRUCTURAL CHANGES WITHIN THE TOTALITY OF THE BIOPHARMA INDUSTRY?

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The “obvious” likely changes;

(1) Skewing away from Small Molecules in Favor of Biologics and “Safe Havens”

(2) Disincentivizing Multiple Indications for Rare Disease Molecules

(3) Upending Traditional Drug Development Paradigms & “Pipeline in a Product” Strategies

(4) Skewing Away from Diseases of the Elderly and Oncology

The “less obvious” possible changes;

(1) Disincentivizing Mergers & Acquisitions involving Small Biotechs

(2) Disincentivizing Public-Private R&D Partnerships

(3) General Impact of Revenue Reductions on the **“Innovation Ecosystem” – How Bad?**

CONCLUSION: Reduction in revenues and profit very likely. Industry will reduce and adjust R&D in response.

EXHIBIT 3: CHANGE R&D INVESTMENT APPROACH IN THE BIOPHARMA INDUSTRY – THE INNOVATION IMPACT

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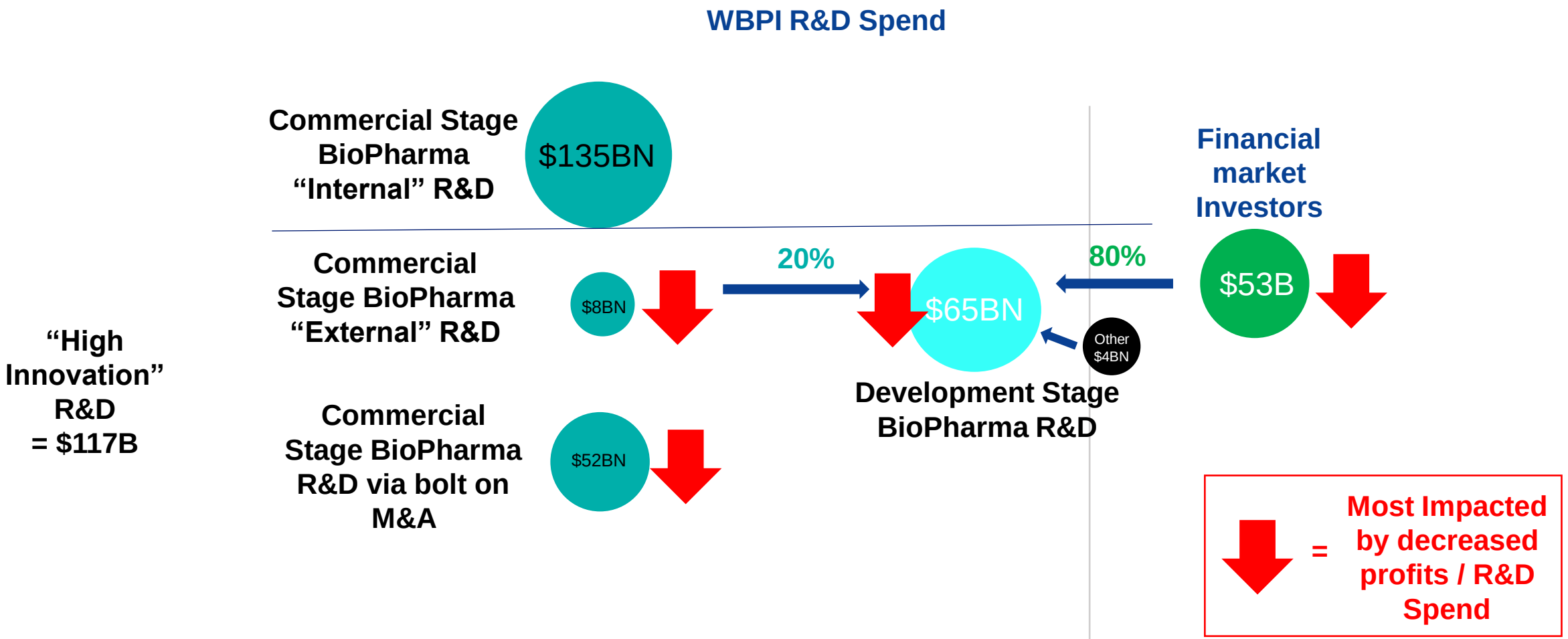

CONCLUSION : A >20% hit to operating income will likely hit "High Scientific Uncertainty" R&D the most


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Alliance FOR AGING RESEARCH

Catalyzing Innovation for Healthy Aging

Michael Ward
Vice President
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About the Alliance

- Started in 1986 to advocate for federal investment in aging-related diseases at the National Institutes of Health; have been part of efforts that have resulted in substantial increases in appropriations for research into aging-related disease

- Policy focus broadened to foster older adults' ability to access high-quality care and support the ongoing development of therapeutics in areas of unmet clinical need

- Diverse efforts include direct patient, provider, and caregiver education materials and training patients to advocate in the field of patient-centered outcomes research

Confluence of cost containment and treating complex conditions

- **Sentiment that U.S. not getting what it pays for in terms of healthcare dollars**
- **Every sector has a turn in the spotlight for healthcare reform efforts – in recent years, it has been drug manufacturers and pricing**
- **Implications for patients in disease states with substantial unmet medical need:**
  - Medicare and Medicaid programs looking to rein in costs – new drugs seen as non-core drivers of additional spending
  - In some cases, Medicare program creating additional evidentiary standards to validate need for coverage
- **Societal prioritization – access or cost containment?**

Push/Pull of Patient Access and the IRA

- **Reduced financial barriers to access as a result of Medicare beneficiary affordability reforms**
- **Uncertainty around impacts of drug negotiation program and Part D redesign**
  - Patient advocate concerns about use of QALYs, evLYG and disproportionate impacts on older adults, individuals with disabilities
  - Does CMS see endpoints identified as important to patients as valuable or concerned their use could increase “maximum fair price” for drugs/biologics?
  - Greater plan liability = increased utilization management?
  - Differentiating impacts of negotiation from UM
- **Problematic incentives in law may harm meaningful clinical development**
  - Negotiation exemption only for drugs with single orphan indication
  - Legislative changes unlikely in near term

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Catalyzing Innovation for Healthy Aging

IVI INNOVATION AND VALUE INITIATIVE

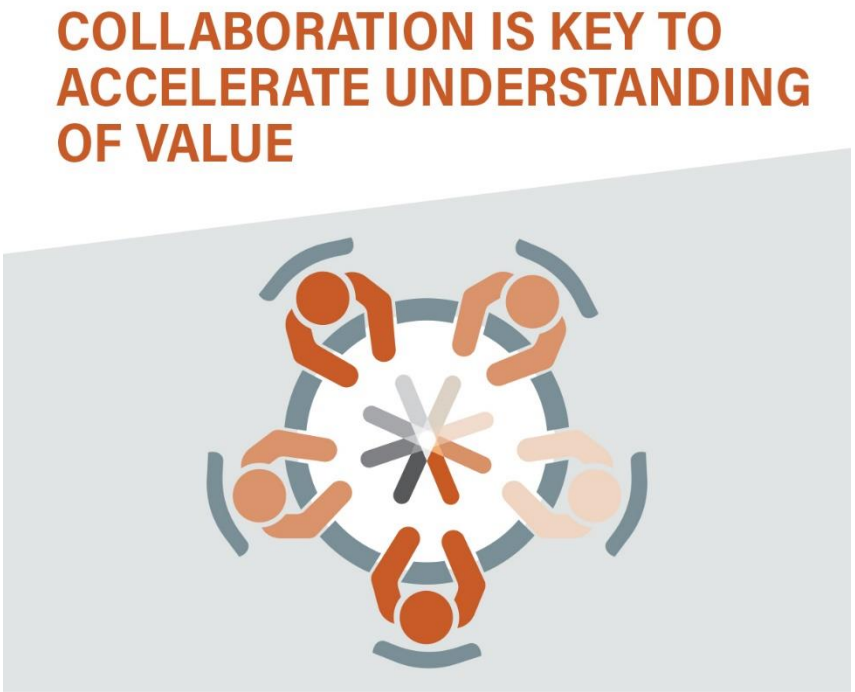
Considering the Impact of the Inflation Reduction Act on Drug Development and Patients

May 8, 2023

IVI: Convener and Builder

MISSION: To advance the science, practice, and use of patient-centered health technology assessment to support decisions that make healthcare more meaningful and equitable.

- The **Innovation and Value Initiative** (IVI) is an independent, 501(c)(3) research organization
- IVI is working to evolve the methods of health economics to support healthcare decisions focused on maximizing patient-centered value

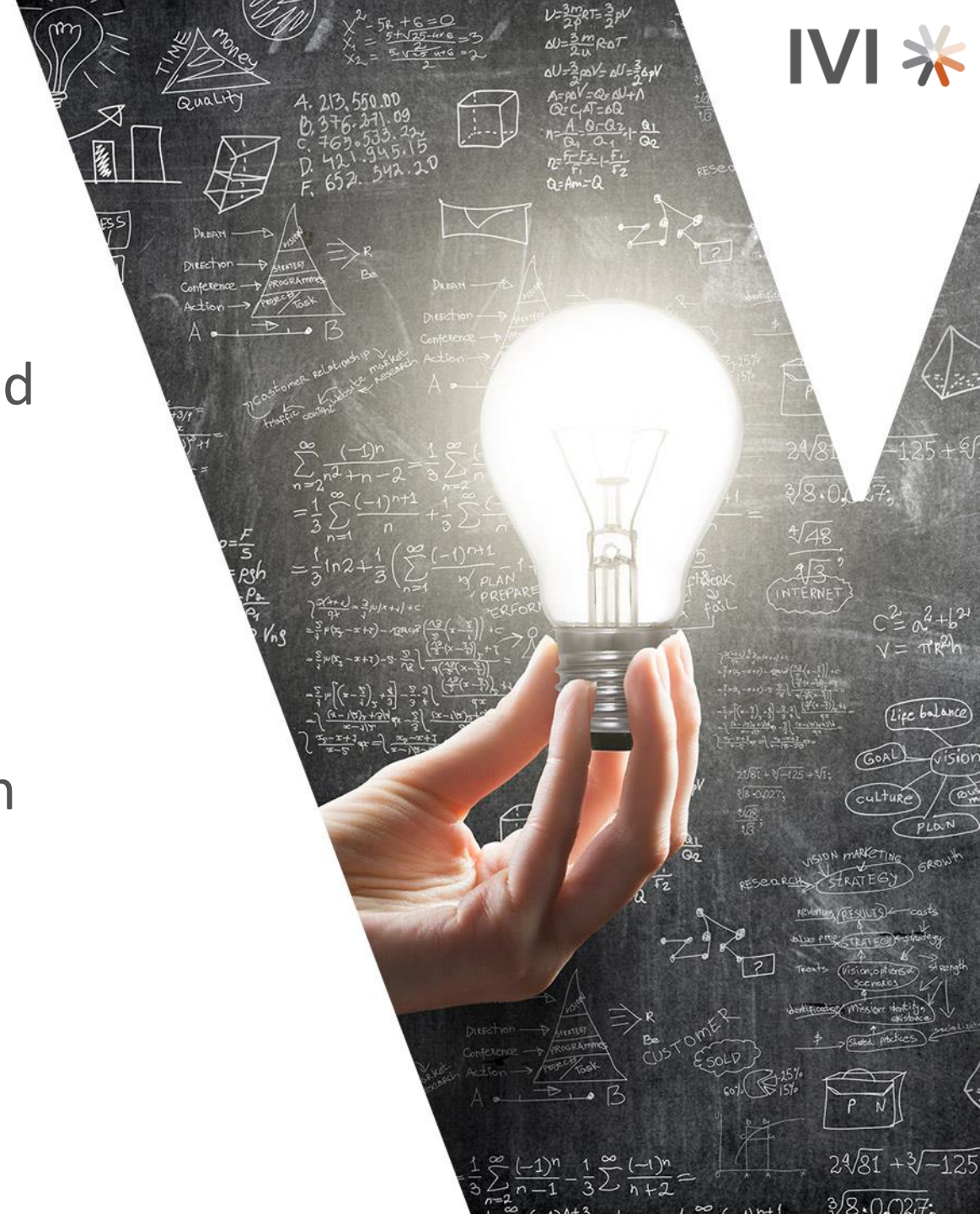


HTA and the Medicare Drug Price Negotiation Program (Medicare DPNP)

- Focus on maximizing value, not minimizing prices.
- Ensure health equity informs all aspects of the DPNP.
- Elevate patient voices systematically.
- Clarify and specify methodological approach.
- Develop forward-looking, long-term strategy.

Focus on maximizing value, not minimizing prices.

- Patient care decisions should be based on value not budget concerns.
- More data elements are needed than initially provided by the draft guidance.
- CMS has opportunity to set a precedent by establish a framework with broader concepts of value.



Ensure health equity informs all aspects of the DPNP

- Health equity is the first pillar in CMS's strategic plan.
- Our work in health equity has identified key themes: **fundamental change**, **accountability**, **meaningful engagement**, **data/methods**, and **transparency**.
- Specific actions:
  - Align guidelines with equity goals;
  - Evaluate potential bias of evidence;
  - Create diverse advisory groups;
  - Incentivize data from underrepresented populations.

Elevate patient voices systematically

- Patient engagement needed beyond evidence submission.
- CMS should include formal mechanisms for engagement for those with lived experience.
- Specific measure needed to ensure patients as equal stakeholders, including patient researchers on CMS evaluation teams.

Clarify and specify methodological approach

- Descriptive framework of the "qualitative approach" needed.
- Methodological terms require further definition:
  - Therapeutic advance;
  - Clinical benefit;
  - Unmet need;
  - "Other factors."
- QALY issues, including alternative methodologies, must be addressed.

Develop forward-looking, long-term strategy

- Tremendous potential to spur innovations to progress the field.
- Better data and evidence, novel methods, and inclusion of patient subpopulations in the process are all important examples.
- Great opportunity to shape research priorities, advance mixed methods approach, and generate more evidence.
- The ultimate goal is a patient-centric, transparent, equitable, value-driven healthcare system.

Additional considerations (toward a US HTA?)

- Will CMS use outside assessments?
- Will CMS create its own HTA?
- One assessment vs. multiple?
- Resources and timing

IVI INNOVATION AND VALUE INITIATIVE

Thank You

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Panel discussion

Considering the Impact of the Inflation Reduction Act on Drug Development and Patients

Audience Q&A

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