# Value-Based Contracts Presentation to PCF Pharmaceutical and Medical Device Compliance Congress

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# Agenda

- Market forces increasing demands for value
- The Value Collaborative
- Innovative, value-based contracting

# We Are In A New Era of Medicine

## THEN

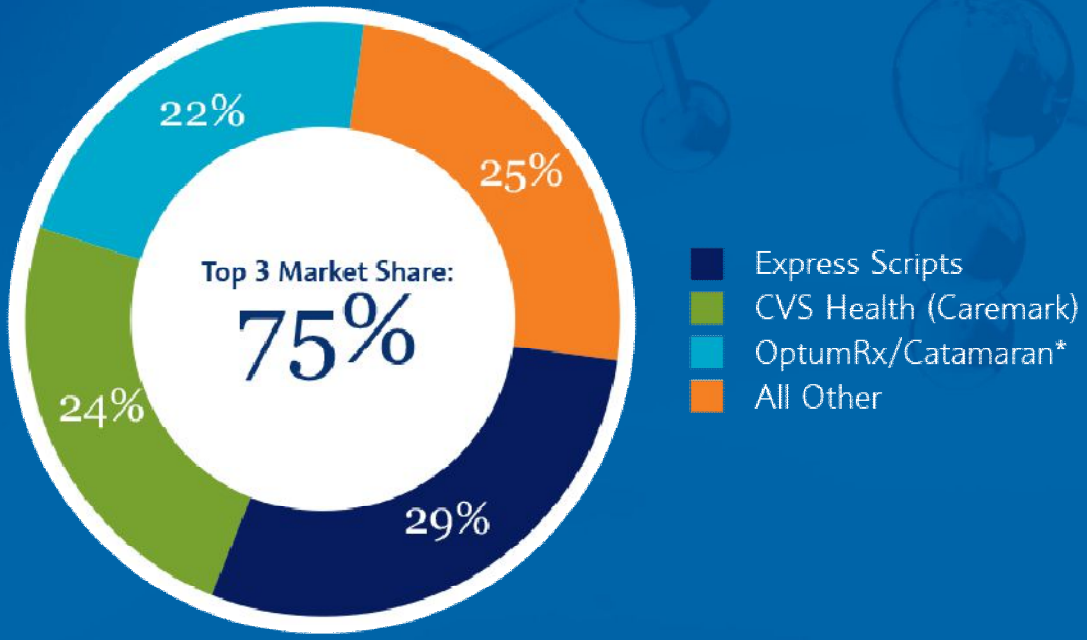
- Medicines made of chemical compounds
- Medicines treat broad diseases
- Attack cancer with radiation and chemotherapy

## NOW

- Medicines made from living cells
- Medicines targeted to specific patient based on genetic makeup
- Attack cancer using body's own immune system

# Payers Have Significant Leverage to Negotiate Rebates and Discounts

## PBM Market Share, by Total Equivalent Prescriptions




## Insurers and PBMs determine:

**FORMULARY**
if a medicine is covered

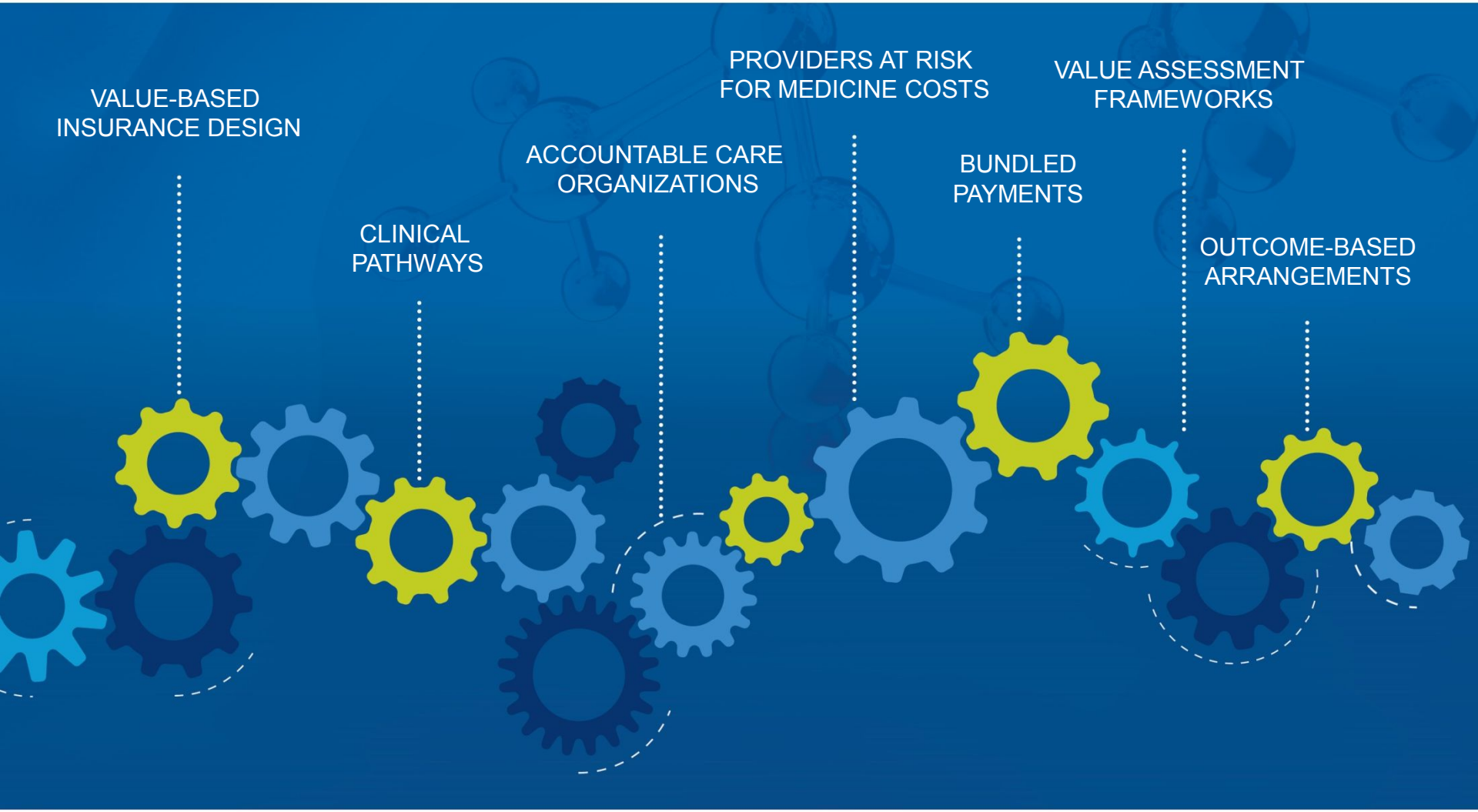
**TIER PLACEMENT**
patient cost sharing

**ACCESSIBILITY**
utilization management through prior authorization or fail first

**PROVIDER INCENTIVES**
preferred treatment guidelines and pathways

NOTE: OptumRx and Catamaran merged in 2015. Their 2014 shares are shown combined.
Source: Drug Channels Institute.

# Payment For Providers And Medicines Is Increasingly Value-driven

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# Provider Accountability For Cost And Pathway Compliance Is Influencing Prescribing Decisions

| | THEN | NOW |
|---|---|---|
| Patients in health plans that incentivize providers to prescribe certain treatments* | **37%** 2014 | **88%** 2016 (*Projected*) |
| Hospital participation in accountable care organizations responsible for cost of care** | **6%** 2011 | **25%** 2014 |
| Medicare payments tied to alternative payment models which include cost or quality incentives*** | **0%** 2009 | **30%** 2014 |
| Commercial market payments where provider is at-risk for cost of care**** | **6%** 2013 | **21%** 2014 |

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*Source: EMD Serono, "Specialty Digest: Managed Care Strategies for Specialty Pharmaceuticals, 12th Edition."
**Source: American Hospital Association, "AHA Hospital Statistics: 2016 Edition."
***Source: U.S. Department of Health & Human Services. HHS reaches goal of tying 30 percent of Medicare payments to quality ahead of schedule.
****Source: Catalyst for Payment Reform. 2013 / 2104 National Scorecard on Payment Reform."

# Policies To Advance A Value-driven Healthcare System

Advance value assessment frameworks and data

Expand value-based contracts and partnerships

Improve capacity for quality measurement

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# PhRMA Is Supporting Development of Patient-centered Value Frameworks And Tools


Faster Cures initiative to develop a **patient perspective value framework**

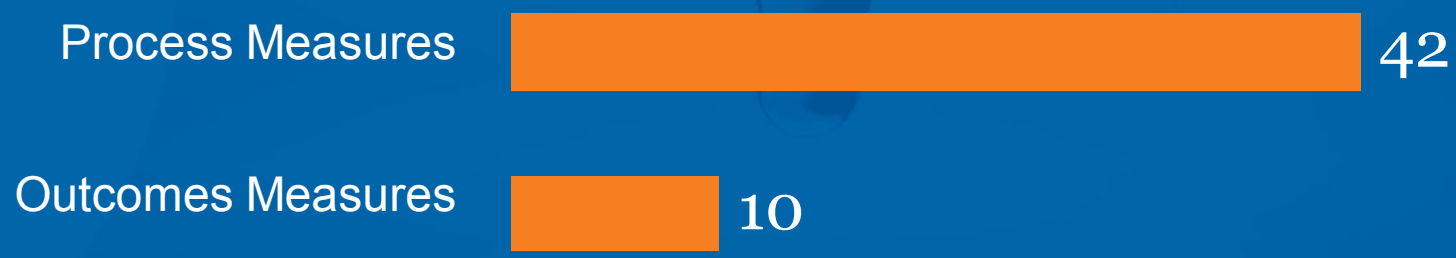
**Initiative on Value and Innovation** to advance a sound value assessment framework

**PhRMA Foundation grant program** to build capacity for rigorous, holistic value assessment

# Outcomes Measurement Is Central To a Value-Based System

Today, the majority of quality measures focus on process, not outcomes

**Clinical Quality Measures identified by the Core Measures Collaborative:**

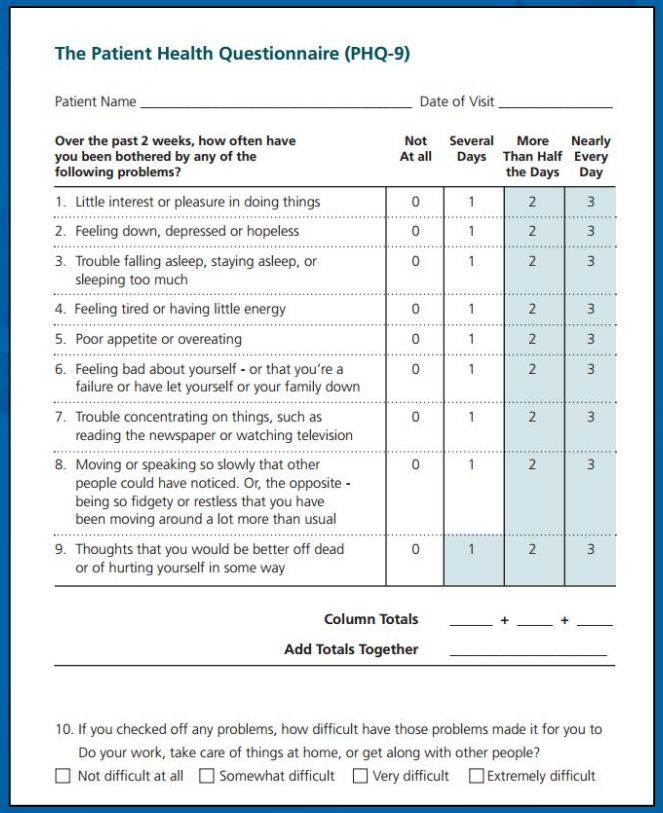


# Patient Reported Outcomes: An Area Of Opportunity

**How do we build these into systems so they are being collected and reported upon regularly?**

## Example Measure:

Percentage of patients 18 years of age or older with major depression or dysthymia who demonstrated a response to treatment 12 months (+/- 30 days) after an index visit



**The Patient Health Questionnaire (PHQ-9)**

Patient Name _____ Date of Visit _____

| Over the past 2 weeks, how often have you been bothered by any of the following problems? | Not At all | Several Days | More Than Half the Days | Nearly Every Day |
|---|---|---|---|---|
| 1. Little interest or pleasure in doing things | 0 | 1 | 2 | 3 |
| 2. Feeling down, depressed or hopeless | 0 | 1 | 2 | 3 |
| 3. Trouble falling asleep, staying asleep, or sleeping too much | 0 | 1 | 2 | 3 |
| 4. Feeling tired or having little energy | 0 | 1 | 2 | 3 |
| 5. Poor appetite or overeating | 0 | 1 | 2 | 3 |
| 6. Feeling bad about yourself - or that you're a failure or have let yourself or your family down | 0 | 1 | 2 | 3 |
| 7. Trouble concentrating on things, such as reading the newspaper or watching television | 0 | 1 | 2 | 3 |
| 8. Moving or speaking so slowly that other people could have noticed. Or, the opposite - being so fidgety or restless that you have been moving around a lot more than usual | 0 | 1 | 2 | 3 |
| 9. Thoughts that you would be better off dead or of hurting yourself in some way | 0 | 1 | 2 | 3 |

**Column Totals** _____ + _____ + _____

**Add Totals Together** _____

10. If you checked off any problems, how difficult have those problems made it for you to Do your work, take care of things at home, or get along with other people?

☐ Not difficult at all ☐ Somewhat difficult ☐ Very difficult ☐ Extremely difficult

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# What Are Value-Based Contracts?

- Voluntary arrangements between manufacturers and other private entities (health plans, risk-bearing providers) in which the price or price-concession for a prescription medicine is linked to value as determined by the contracting entities

- These contracts may tie payment for a new medicine to the outcomes it delivers, or otherwise reduce the risk borne by insurers

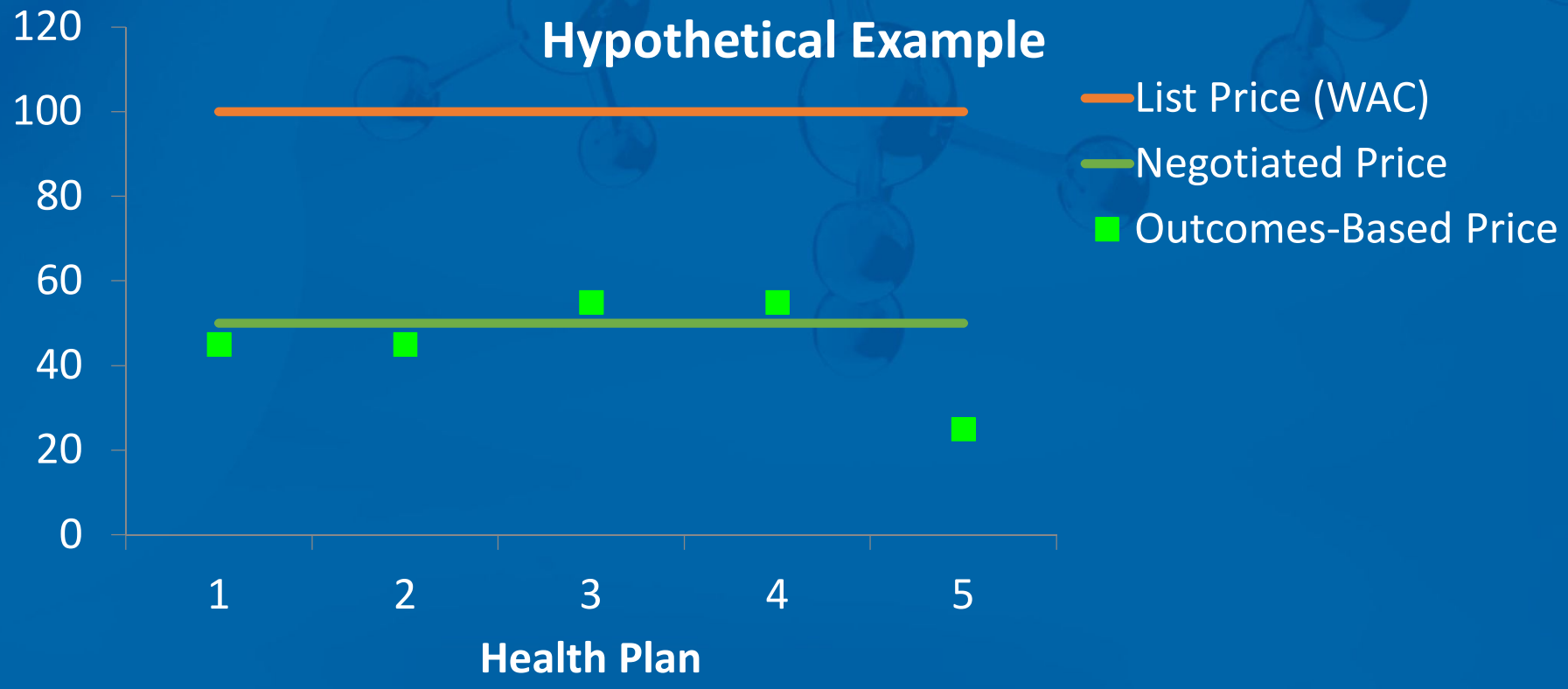
- Value-based contracts are <u>not:</u>
  - Phase II of the Part B Drug Payment Model
  - MedPAC proposed “Drug Value Program”
  - Other mechanisms for “value-based” govt. price setting

# Benefits Of Addressing Public Policy Barriers That Limit Number/Scale Of Value-based Contracts

- Allow for new negotiations between private payers and biopharmaceutical industry around product value
- Improve patient access through fewer coverage restrictions
- Lower cost sharing for medicines due to better formulary placement
- Develop evidence about how innovative medicines can be used most effectively to improve outcomes

# Specific Example 1:
# Outcomes- Or Performance-Based Contract

A manufacturer agrees to vary the final price paid by a payer based on how well the drug improves outcomes for patients, or other endpoints

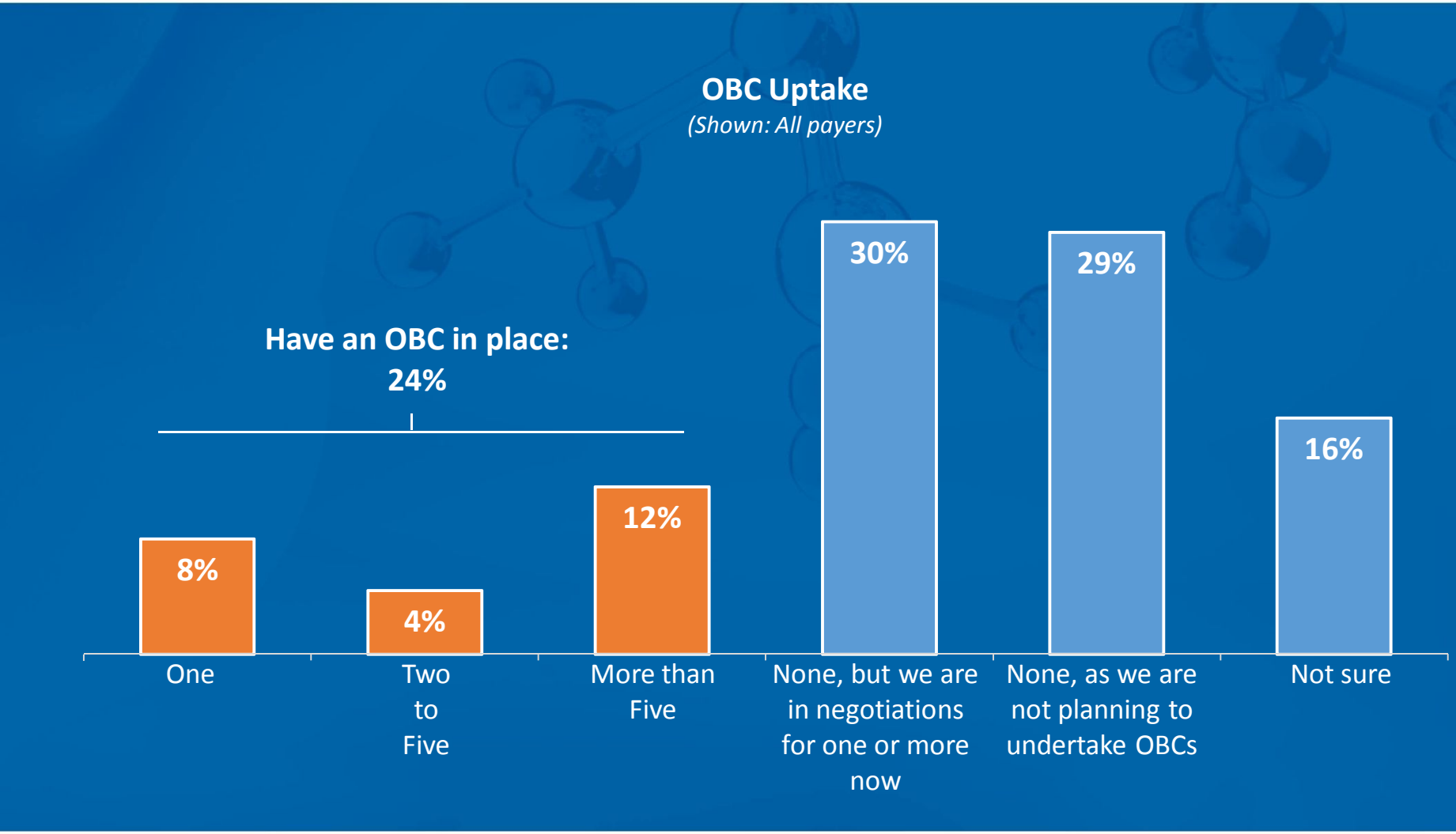


# Public Examples Of Performance-Based Contracts

| Parties | Drug | Indication | Metric |
|---|---|---|---|
| Harvard Pilgrim / Eli Lilly | Trulicity | Diabetes | **Number of patients meeting Hemoglobin A1c target compared to other GLP-1 receptor antagonists** |
| Aetna / Novartis | Entresto | Heart Failure | **Reduction in hospitalization rate, and overall savings to payer** |
| Cigna / Amgen | Repatha | Cholesterol-lowering | **Reduction in low-density lipoprotein cholesterol levels** |
| Express Scripts / AstraZeneca | Iressa | Lung cancer | **Number of patients who fill the medicine three times** |

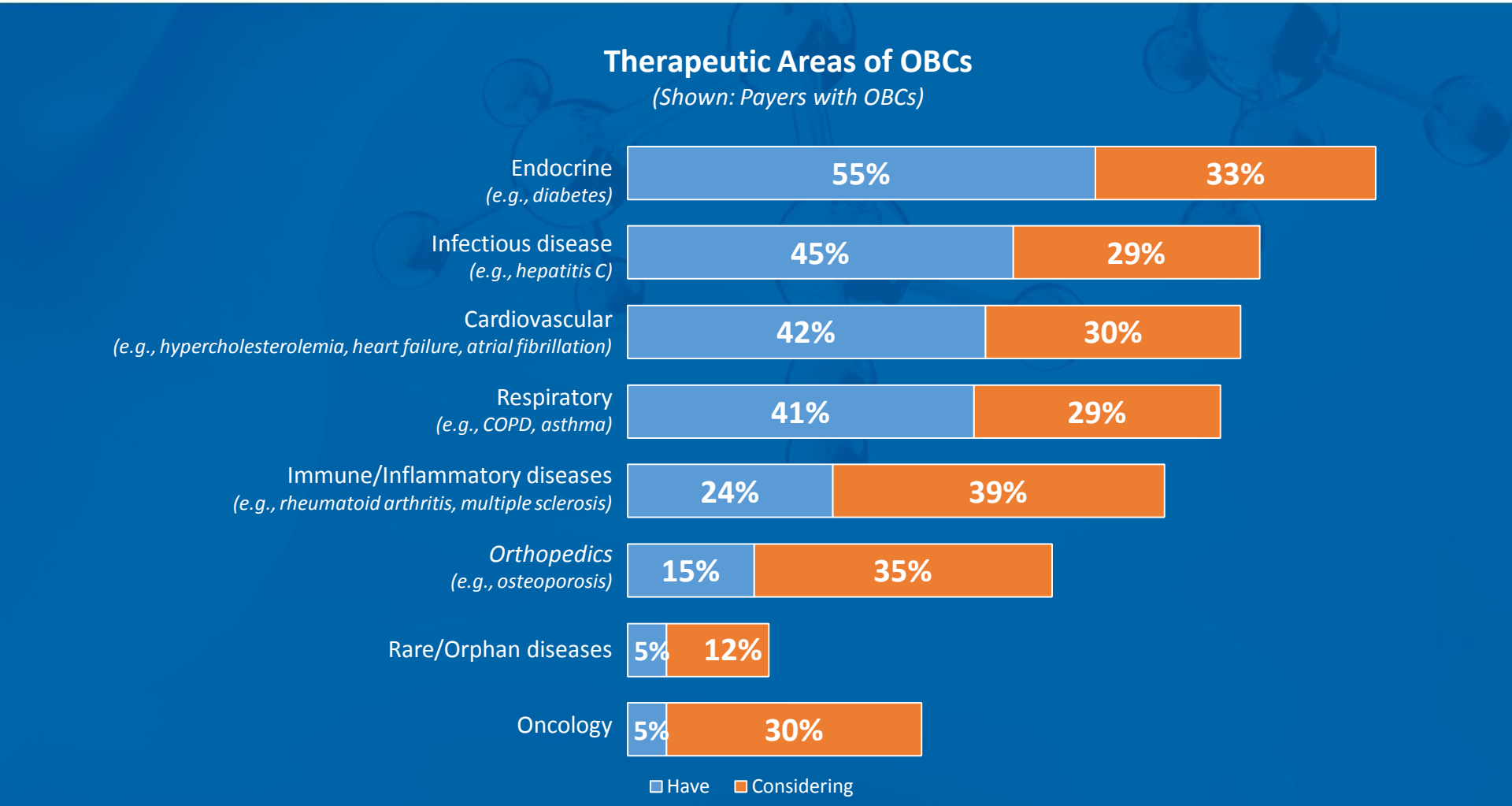
Source: NEHI. Rewarding Results: Moving Forward on Value-Based Contracting for Biopharmaceuticals. March 2017.

# Half Of Payers Are Pursuing Outcomes Based Contracts




Source: 2017 Avalere Health Survey of 45 unique payers, including 8 of the 10 largest health insurers in the U.S, which in total represent 183M covered lives in the U.S.

# Outcomes Based Contracts Are Being Implemented And Explored In Many Treatment Areas




Source: 2017 Avalere Health Survey of 45 unique payers, including 8 of the 10 largest health insurers in the U.S, which in total represent 183M covered lives in the U.S.

# Specific Example 2: Indication-Based Pricing

- A manufacturer agrees to be paid differently for different uses of its medicine

| Indication | How Effective? (metric negotiated within contract) | 'Example negotiated 'value'/price |
|---|---|---|
| Breast Cancer | Highly | $100 |
| Lung Cancer | Minimally | $20 |

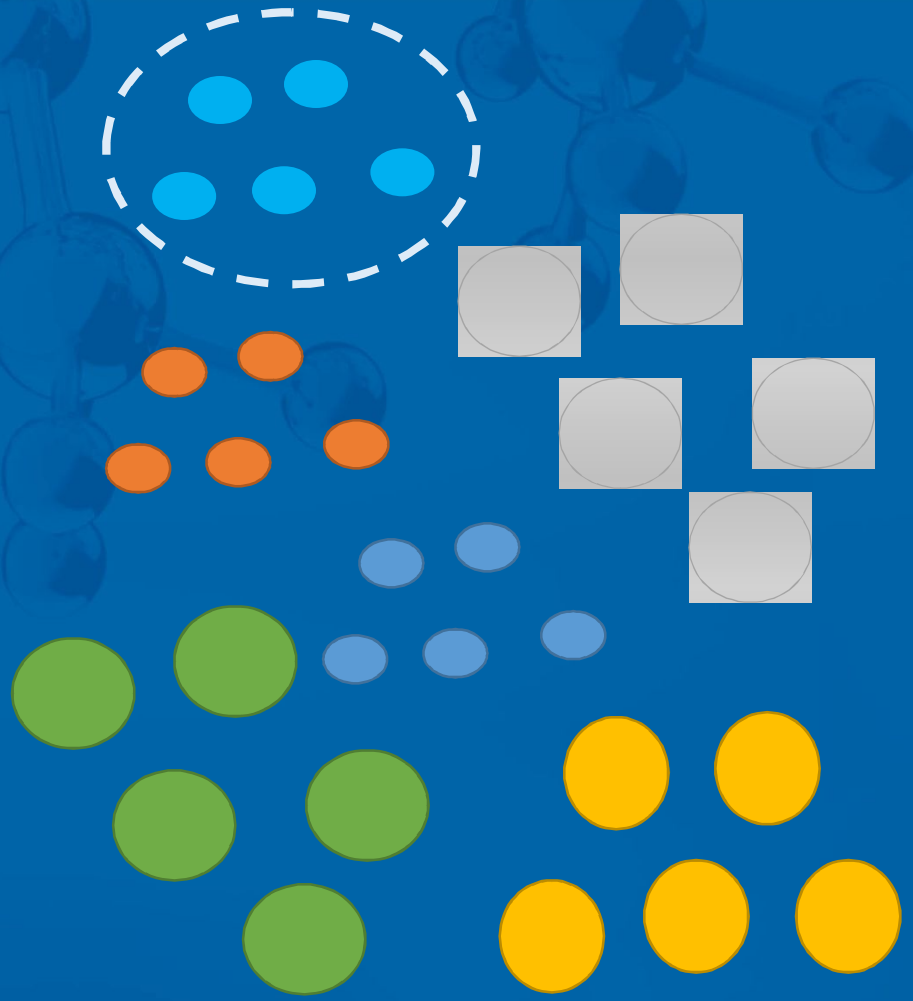
- Actual price paid might be a blended price based on how much of the drug is expected to be used for each indication

- *CVS and Express Scripts have both announced that they are implementing indication-based pricing for oncology*

# Value-Based Contracts Are Allowed Today

- Companies have found a way to engage in value-based contracts while complying with existing laws and regulations

- However, if regulations were modernized, **more** of these contracts would happen and the **scale** of the contracts would likely be greater



# Need To Develop A Clear Path Forward

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# Recommendations To Enable Value-Based Contracts

**Modernize regulations that have the effect of limiting the number and scope of value-based contracts**

- **Anti-Kickback Statute**
  - Value-based contracts should be clearly protected under the anti-kickback statute
- **Price Reporting**
  - Price reporting rules need to be modernized to enable value-based contracting at a larger scale
- **FDA regulations and guidance governing manufacturer communications**
  - Manufacturers need flexibility to communicate broadly about products with payers and population health decision makers

# Anti-Kickback Statute

- Broad, vague law that prohibits providing ***anything of value*** with the ***intent to influence*** purchase/use of items or services reimbursed by ***federal healthcare programs***

# Anti-Kickback Statute – Exceptions and Safe Harbors

- To protect beneficial arrangements that otherwise might implicate the anti-kickback statute, policymakers created exceptions (legislative) and safe harbors (regulatory)
- The key safe harbors for the industry are over 20 years old
- There should be clear protection for value-based contracts and associated services under the anti-kickback statute

# Manufacturer Communications

- Manufacturers need greater flexibility to communicate about their products with payers and population health decision makers

**Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities**

***Q. A.11. What are the Agency's policies regarding risk-sharing and other value-based contracts between firms and payors?***

A. A.11. This guidance addresses the communication of HCEI to payors, which may include communication of HCEI in the course of discussions between firms and payors related to risk-sharing and other value-based contracts. This guidance, however, is not intended to address the terms of contracts between firms and payors. FDA does not regulate the terms of contracts between firms and payors.

# Recent FDA Activity on Manufacturer Communications

| Audience | Investigational products | Approved Products | |
|---|---|---|---|
| | | Approved Uses | Unapproved Uses |
| **Payers & Population Health Decision Makers** | **Draft Guidance:** Drug And Device Manufacturer Communications With Payers, Formulary Committees Or Similar Entities | | • **Final Rule:** Amendments to Regulations Regarding "Intended Uses"<br>• **Open Docket:** Manufacturer Communications Regarding Unapproved Uses of Approved or Cleared Medical Products<br>• **Memorandum:** Public Health Interests and First Amendment Considerations Related to Manufacturer Communications Regarding Unapproved Uses of Approved or Cleared Medical Products |
| **Health Care Professionals** | No Recent Changes | **Draft Guidance:** Medical Product Communications that are Consistent with the FDA-Required Labeling | |

# Many Unapproved Uses of Medicines are Medically-Accepted

**Examination of medically accepted unapproved uses for 46 branded medicines from CMS-recognized compendia used for Medicare or Medicaid payment purposes**

| | NCCN Compendium | DRUGDEX Compendium |
|---|---|---|
| Medicines with Any Recommendation for Unapproved Use | 31 (67%) | 15 (33%) |
| Types of Unapproved Use* | | |
| Additional Combinations Not Included on the Label | 27 (59%) | 7 (15%) |
| Subpopulations not Included in the Main Indication | 8 (17%) | 0 |
| Use in Alternative Disease Progression (e.g. Lines of Therapy) | 29 (63%) | 1 (2%) |
| Recommendations on Other Aspects Considered for Diagnosis (e.g. pregnancy, diagnostic test results, or genetic test results) | 13 (28%) | 0 |

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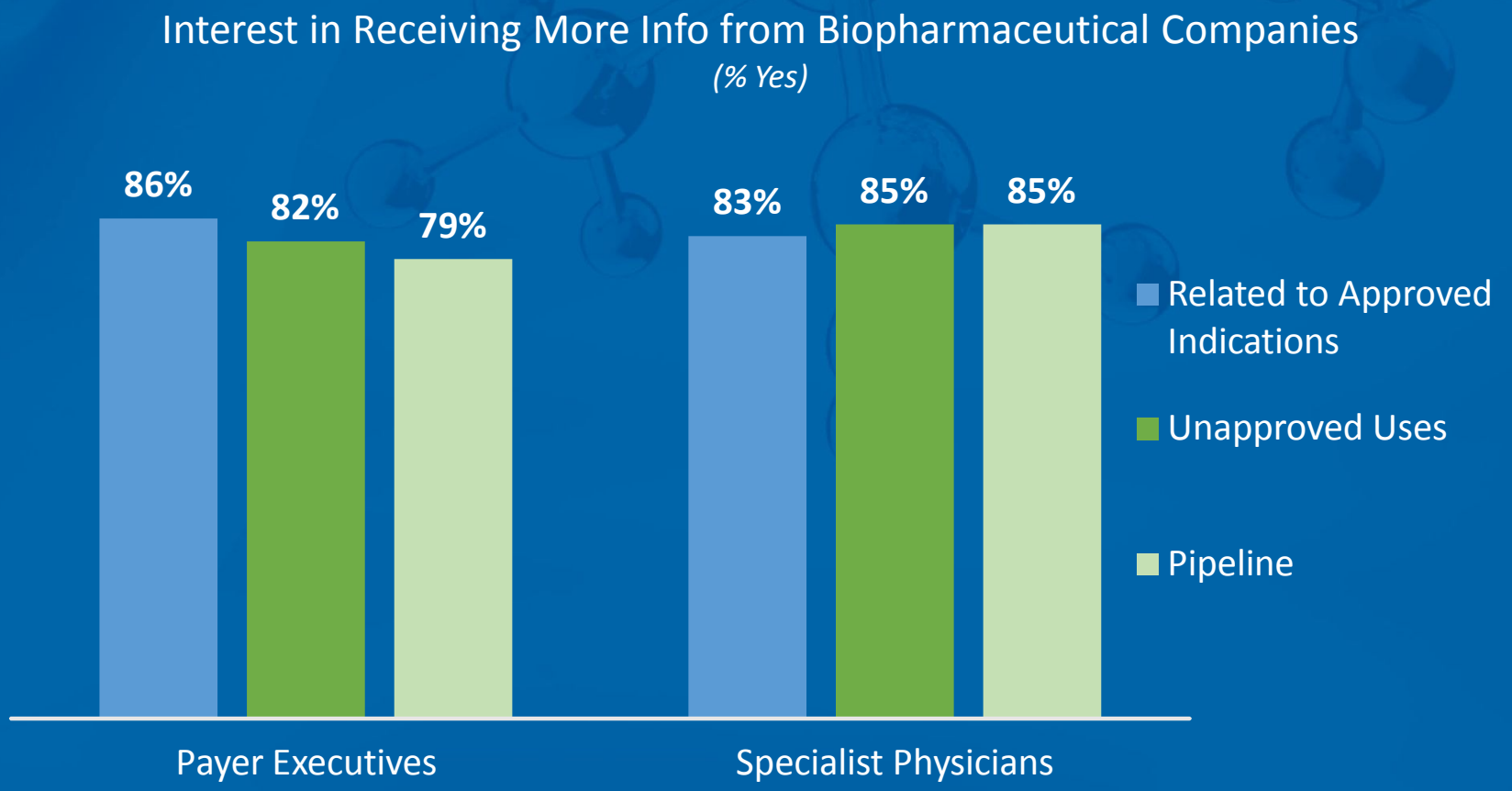
*Medicines, on average, had 1.71 (NCCN) and 1.53 (DRUGDEX) recommendations for an unapproved indication. As a result, the numbers for "Types of Unapproved Use" do not sum to the number displayed in the first row.

# Payers and Providers Want More Information From Manufacturers




n=39 executives, n=178 physicians.
Source: Health Strategies Group, Custom Research, December 2016.

# A Responsible Path Forward

FDA should define clear standards governing *responsible, truthful and non-misleading communications* to inform health care professionals and payers about the safe and effective use of medicines

**Key principles should include:**

- Science-based communication
- Provide appropriate context about data
- Tailoring communications to the intended audience

The PhRMA-BIO Principles pertain primarily to data and information outside of FDA-approved labeling, such as additional clinical trials or analysis of real-world patient outcomes


PRINCIPLES

PRINCIPLES ON RESPONSIBLE SHARING OF TRUTHFUL AND NON-MISLEADING INFORMATION ABOUT MEDICINES WITH HEALTH CARE PROFESSIONALS AND PAYERS

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INTRODUCTION

KEY CONCEPTS OF THE PRINCIPLES (INCLUDE OUR MEMBERS)

# Don’t Ignore the Operational Challenges

- The number of outcomes-based contracts may be limited by measurement challenges
- Other types of contracts – that are easier to operationalize – could also be supported by modernized regulations
- Legal barriers, such as the anti-kickback statute, and FDA rules can also limit the biopharmaceutical industry’s ability to manage operational challenges
- The market is working to address the operational challenges, but legal obstacles require public policy solutions

# Administration Interest in Value Based Contracts

**President's Budget**

- "The Budget also includes a package of administrative actions…These actions include…Clarifying treatment of value-based purchasing arrangements."

**CMS Press Release 8/30**

- "CMS will be issuing future guidance to explain how pharmaceutical manufacturers can engage in innovative payment arrangements"… Through CMMI, "CMS will aim to identify and alleviate regulatory barriers in Medicare and Medicaid as may be necessary to test payment and service delivery models that involve value-based payment arrangements."

**CMMI New Direction RFI**

- "CMS wants to test new models for prescription drug payment, in both Medicare Part B and Part D and State Medicaid programs that incentivize better health outcomes for beneficiaries at lower costs and align payments with value… including, but not limited to innovative value based purchasing arrangements."