From Resilience To Growth:

Mapping a New Direction for Life Sciences & Medical Devices

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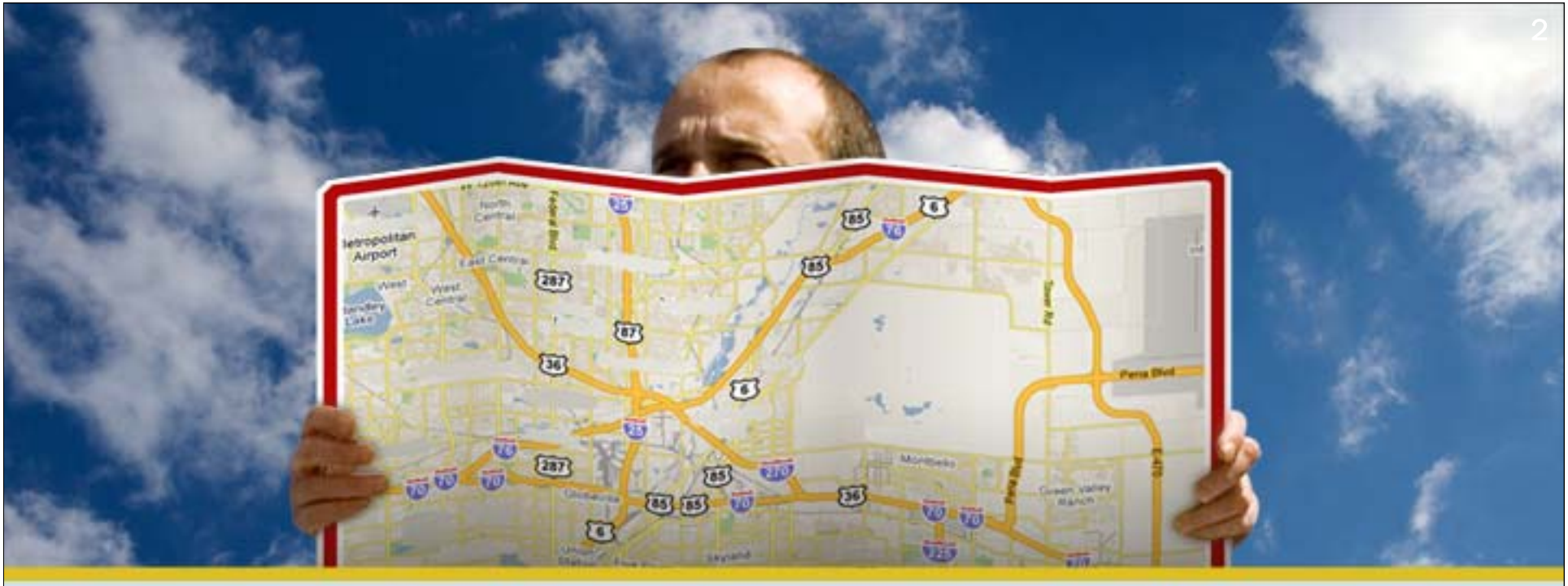

Growth Strategy: Evidence Based Reimbursement & Commercialization Strategies for Innovators & Investors

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Panelists:

- **Judith A. Waltz**, Partner, Co-Chair, Life Sciences Industry Team and member, Government Enforcement, Compliance & White Collar Deference Practice, *Foley & Lardner*

- **Anita Chawla**, Ph.D., Vice President, *Analysis Group*

Road Map

- Medicare product coverage strategy
- Proper planning for product pricing
- Preparing comparative effectiveness data
- Working with payer expectations
- Data that should be in place for partnering or acquisition deals

Medicare Product Coverage Strategies

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Medicare - Introduction

- **Medicare** is a federal program which covers the aged and disabled based on quarters of coverage from employment or length of disability. Expenditures of $468.1 billion in 2008.
  - Part A – Institutional care (e.g. hospital) – 45 million beneficiaries in 2008
  - Part B – Certain medical services (e.g. physician) and supplies (e.g. DME) – 42 million beneficiaries in 2008
  - Part C – Managed Care
  - Part D - Prescription Drugs - 32 million beneficiaries in 2008
- **Medicaid** (Medi-Cal in California) is a needs and categorically-based program unique to each state which is partially funded by the federal government.

Source: *Brief Summaries of Medicare and Medicaid (as of November 1, 2009), available at* http://www.cms.gov/MedicareProgramRatesStats/Downloads/MedicareMedicaidSummaries2009.pdf

2010 Affordable Care Act (ACA)

- Patient Protection and Affordability Act and Health Care and Education Reconciliation Act (Pub.L. 111-148, a/k/a H.R. 3590, and Pub. L. 111-152, a/k/a H.R. 4872) – finalized by President Obama's signatures on March 23 and 30, 2010
- Consolidated language compiled by the House Legislative Counsel now available at http://www.premierinc.com/about/advocacy/issues/10/healthcarereform/PPACA-CONSOLIDATED.pdf
- Foley.com/HCReform (resource site)

ACA Defines and Expands Medicare "Preventive" Services

- Specific services listed by statute with exclusion of ECG
- Initial preventive physical exam
- Annual wellness visit

- *Significance: a change in focus from Medicare's traditional limitation to diagnosis/treatment of a particular illness or disability to preventive and personalized care.*

ACA Provisions - Medicare Annual Wellness Visit (Section 4103)

- Medicare will provide coverage for an annual "wellness visit" (previously just a “Welcome to Medicare” visit)
- The annual wellness visit should include a personalized prevention plan for an individual that takes into account the results of a health risk assessment.
- The prevention plan should provide personalized health advice aimed at reducing identified risk factors and improving self-management of an individual's health care and treatment.
- Health risk assessments will be based on guidelines developed by the Secretary. The assessments will identify chronic diseases, modifiable risk factors, and emergency or urgent health needs. (Guidelines not yet done as of release of Physician Fee Schedule in June 2010.)

ACA Provisions – Covered Complex Diagnostic Tests (Section 3113)

- Authorizes the Secretary to conduct a demonstration project to allow separate payment under Medicare Part B
- Limited to covered complex diagnostic tests (as defined by the Act) that link a patient's genetic makeup to a cancer chemotherapy where no alternative test is available having equivalent performance characteristics, under certain limited circumstances
- Payment rates to be determined by the Secretary
- Limited to tests on patient samples collected during hospitalization but performed after hospitalization
- Will ultimately result in a report to Congress with an assessment of the project's impact on access to care, quality of care, health outcomes, and Medicare expenditures (including savings)

Medicare Coverage: Genetic Tests

Considerations in seeking coverage:

- ✓ Provide adequate evidence that
- ✓ The incremental information obtained by new diagnostic technology compared to alternatives
- ✓ Changes physician recommendations
- ✓ Resulting in changes in therapy
- ✓ That improve clinically meaningful health outcomes
- ✓ In Medicare beneficiaries

Source: CMS (James Rollins and Jeffrey Roche) Presentation to Personalized Medicine Coalition, entitled *"Evidence, Medicare Coverage and Diagnostic Genetic Testing,"* discussing MEDCAC's Recommendations to CMS (March 2010)

FDA/CMS Parallel Approvals

FDA/CMS Request for Comments

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FDA/CMS Parallel Review (Proposed)

- Request for comments issued September 2010; comments due 90 days after date of publication.
- Provides a series of questions to invite comments.
- Intended to reduce the time between FDA marketing approval or clearance decisions and CMS national coverage determinations (NCDs).
- Also announces intent to create a pilot program for parallel review of medical devices.

FDA/CMS Parallel Review (cont.)

- Under current practice, CMS does not routinely start NCD process until after FDA approval or clearance.
- Parallel process can educate product developers about clinical study designs that will address both CMS and FDA needs.
- FDA/CMS contemplate voluntary “opt-in.”
- Process to be staged so as to meet deadlines.

FDA/CMS Parallel Review (cont.)

Questions Suggested in the Request for Comments

- Disadvantages to parallel review
- Identify legal, regulatory and/or scientific considerations which pose barriers to the parallel review process
- Transparency vs. confidentiality – how to balance
- Resource limitations at both agencies which may limit the number of parallel reviews?
- Prioritizing classes of products for parallel review?
- Criteria for granting parallel review?
- Who can request parallel review besides the industry sponsors: CMS, FDA or interested third parties?

Proposed Legislation

Support for Personalized Medicine

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The Genomics and Personalized Medicine Act of 2010 (H.R. 5440)

- Introduced on May 28, 2010 by Reps. Patrick J. Kennedy, D-R.I., and Anna Eshoo, D-Calif.
- A similar bill was previously introduced by then-Sen. Barack Obama, D-Ill., during the 110th Congress.
- The overall goal of the act is to realize the promise of personalized medicine by expanding and accelerating genomics research, improving the accuracy of disease diagnosis, increasing the safety of drugs and identifying novel treatments.

H.R. 5440 - Office of Personalized Healthcare

- To be established within the Office of the HHS Secretary to coordinate the activities related to genomics and personalized medicine of HHS and other relevant federal agencies, as well as private and other public entities.
  - The office would oversee selected initiatives to realize the overall goals of the act, such as the development of a long-term strategic plan to advance personalized medicine.

H.R. 5440 - Expansion and Acceleration of Research for Genomics and Personalized Medicine

- If enacted, the secretary will be able to award grants to entities to increase and accelerate research and programs to collect, evaluate and disseminate genetic and genomic data.
- The director of the National Institutes of Health, in consultation with the director of the Centers for Disease Control and Prevention, would establish and maintain a national biobank to advance the field of personalized medicine.

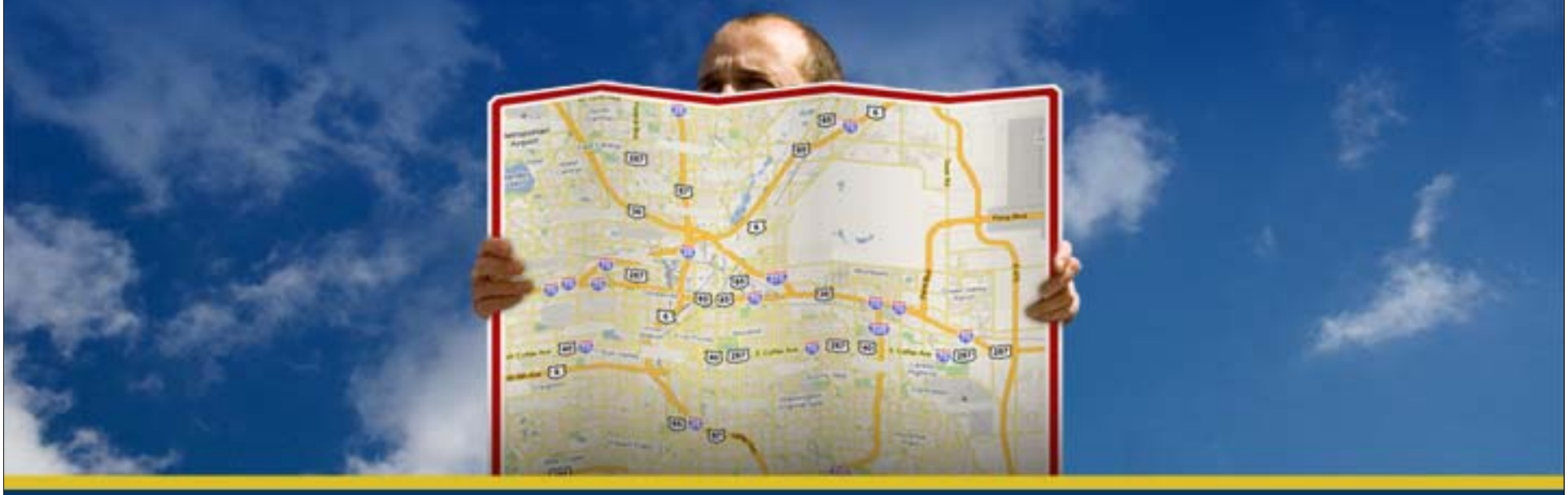
H.R. 5440 - Committee on the Evaluation of Genomic Applications in Practice and Prevention

- The act would create an advisory committee to analyze current literature to expand and accelerate knowledge related to the clinical validity and utility of genomics and personalized medicine. The committee will, for example, develop or adapt processes for recognizing promising new products for the use of personalized medicine.

H.R. 5440 - Realizing the Potential of Personalized Medicine

- The act calls for the study of barriers to the implementation of personalized medicine through various avenues. For example, the secretary would:
  - Establish a committee to carry out a comparative analysis of laboratory requirements to the end of reducing redundancy.
  - Establish a committee including representatives of the private sector to examine barriers in research, regulation and reimbursement for medical product development for personalized medicine.
  - Enter into an agreement with the Institute of Medicine to provide an independent, external review of the current billing, coverage and reimbursement methods for products and services used for personalized medicine.
  - The act also encourages the development of companion diagnostic tests and products in connection with the submission of investigational new drug products.
  - Additionally, the act would implement a review and analysis of the public health impact of direct-to-consumer marketing and access to products used for personalized medicine.

Comparative Effectiveness



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Comparative Effectiveness Research

- Comparative effectiveness research is designed to inform health-care decisions by providing evidence on the effectiveness, benefits, and harms of different treatment options. The evidence is generated from research studies that compare drugs, medical devices, tests, surgeries, or ways to deliver health care.

- There are two ways that this evidence is found:
  - Researchers look at all of the available evidence about the benefits and harms of each choice for different groups of people from **existing** clinical trials, clinical studies, and other research. These are called research reviews, because they are systematic reviews of existing evidence.
  - Researchers conduct studies that generate **new** evidence of effectiveness or comparative effectiveness of a test, treatment, procedure, or health-care service.

- *Source: http://effectivehealthcare.ahrq.gov/index.cfm/what-is-comparative-effectiveness-research1/*

Comparative Effectiveness Research

- Seven steps are involved in conducting this research and in ensuring continued development of the research infrastructure to sustain and advance these efforts:
  - Identify new and emerging clinical interventions.
  - Review and synthesize current medical research.
  - Identify gaps between existing medical research and the needs of clinical practice.
  - Promote and generate new scientific evidence and analytic tools.
  - Train and develop clinical researchers.
  - Translate and disseminate research findings to diverse stakeholders.
  - Reach out to stakeholders via a citizens forum.

AHRQ website

"Comparative Effectiveness Research is out; Patient Centered Outcomes Research is in."

As congressional debate on creating a public/private entity to conduct such research was heating up, Senate Finance Committee Chairman Max Baucus (D-Mt.) Baucus decided that the term "comparative effectiveness research" was becoming too much of a lightning rod for controversy and changed the term in health care reform legislation to "patient-centered outcomes research."

Gregory Twachtman, The RPM Report, *"What's In a Name? The Semantics of CER"* (September 10, 2010)

Patient-Centered Outcomes Research Institute

- ACA Section 6301,
- Nonprofit corporation
- Will identify national priorities for research,
- Will assist in the analysis of health outcomes and the clinical effectiveness, risks, and benefits of more medical treatments such as therapies, diagnostic tools, and pharmaceuticals (e.g., drugs and biologics).
- The research funded must take into account, as appropriate, the potential for differences in the effectiveness of health care treatments in various subpopulations; for example, individuals with different genetic and molecular sub-types.
- Results of the studies are to be published in a format that is comprehensible to patients and providers, with safeguards to protect patient privacy and confidentiality of study subjects.

AARA Funds PCORI

- AARA (aka Stimulus Bill) signed by President Barack Obama in February 2009, authorized $1.1 billion for research on what medical treatments work best for which people. (AARA split funding between the Agency for Healthcare Research and Quality (AHRQ); National Institute for Health (NIH), and HHS
- $17 million of ARRA funds will be used to establish a network of PCOR centers. PCOR stands for "patient-centered outcomes research," also known as "comparative effectiveness research."
- "Patient-centered outcomes research can improve health outcomes by developing and disseminating evidence-based information to patients, providers and decision-makers about the effectiveness of different treatments," said HHS Secretary Kathleen Sebelius.

HHS Press Release, "*HHS Awards $17 Million for Patient-Centered Outcomes Research"* (Sept. 1, 2010).

Medicare – Historical Approach

- Coverage with Evidence-Based Development
- Least Costly Alternative
- Trend towards focus on "outcomes" as part of the quality initiative
- FDA/CMS Sentinel Initiative – shared information about the Medicare population
  - 2011 Budget Justification – focus on increased sophistication of data collection/use so as to be a leader in comparative effectiveness

Roadblocks to CER/PCO approach

- Who pays for the clinical trial to gather comparative data?
- Co-pay differentials encourage patient choices among drugs tested
- How do you bill for an unknown drug, and get to unidentified claims on patient EOBs?
- Statutory authority for alternative payment mechanisms under Medicare, but not implemented
- Martin, McGuire and Fine,"*Roadblocks to Comparative-Effectiveness Research,*" N. Engl. J. Med. 363;2 (July 8, 2010)

Questions??

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Growth Strategy: Evidence Based Reimbursement and Commercialization

Strategies for Innovators and Investors

Foley & Lardner Life Sciences Conference

September 29, 2010

Demands associated with evidence based reimbursement and commercialization have created a new environment

Clinical Utility

- Primary focus on clinical safety & efficacy (inc. surrogate endpoints)
- Most likely placebo comparator

Eligible Patients

- Blockbuster orientation toward broad patient populations

Market Access

- Generally assumed if safety and efficacy meet regulatory hurdle

Commercial Potential

- Focus on market share as a function of clinical comparison to SOC

Clinical Utility

- Primary focus on clinical safety & efficacy around patient outcomes
- Increasing instance of active comparator

Eligible Patients

- Patient selection a critical variable for outcomes and value proposition

Market Access

- ***Access not a "given" in most areas, regardless of regulatory outcome***

Commercial Potential

- ***Economic value vs. competition plays a more important role in access and share gained***

Drivers for evidence will impact both large and small firms

Global economic conditions increase pressure for cost containment

Increasingly competitive global markets with more payer scrutiny will demand stronger evidence packages

Compelling evidence of value for must be generated for multiple stakeholders—physicians, patients, and payers

Large pharmaceutical and biotechnology firms
- Commercialize products
- Licensees or acquirers of products developed by smaller firms

Smaller pharmaceutical and biotechnology firms
- Compete for scarce funding
- License or sell assets

Investors
- Must be prepared to evaluate strength of an asset's value proposition, particularly in the context of reimbursement

Having a clear, early understanding of fundamental value is critical to commercial success

Products will enter competitive markets and be evaluated on relative clinical effectiveness

- With CER, comparisons versus placebo will be insufficient to demonstrate significant clinical benefit

Patients are acting as consumers of health care and taking a bigger role in treatment and decisions as they incur greater financial burden

- Pharmaceutical and biotech companies will need to communicate the effect of treatment on outcomes that are meaningful for patients

More scrutiny of a broader set of evidence by U.S. and Ex-U.S. payers is expected

- Health technology assessment is established in reimbursement evaluation outside the US (e.g., UK and Australia)
- In the US, some payers are starting to evaluate economic evidence in addition to evidence on safety and efficacy

Ideally, planning for evidence based reimbursement and commercialization starts early

Conduct disciplined and systematic assessment of the impact of market, competitive, scientific, regulatory, and clinical conditions on product development and marketing investment decisions

- Establish clear baseline understanding of market and competitive conditions at launch
- Identify key sources of risk and uncertainty, and opportunities for risk mitigation through enhanced clinical program design and outcomes based arrangements
- Future markets will demand that data for approval are just the beginning—they are necessary but not sufficient for market access and physician utilization decisions

Develop road map for evidence generation and communication strategy to respond to the needs of market stakeholders

- Systematic defined link between clinical value and market value
- Specific objectives, strategy, and tactics for addressing market needs, with well defined deliverables and communication plans, and resource needs

Earlier planning increases degrees of freedom and ROI

Phase 1 — Phase 2 (early) — Phase 2 (late) — Phase 3 — Launch

Typical Early-Phase Issues

- Trial design, optimal set of metrics to support market access and physician choice
- Patient sub-groups most likely to benefit
- Indication sequencing
- Prioritization of development resources, go/no go decision making

Value Planning and Payer Research

- Early pricing and market landscape assessment
- Assess evidence based review of analogues
- Test positioning with stakeholders
- Health outcomes simulation modeling

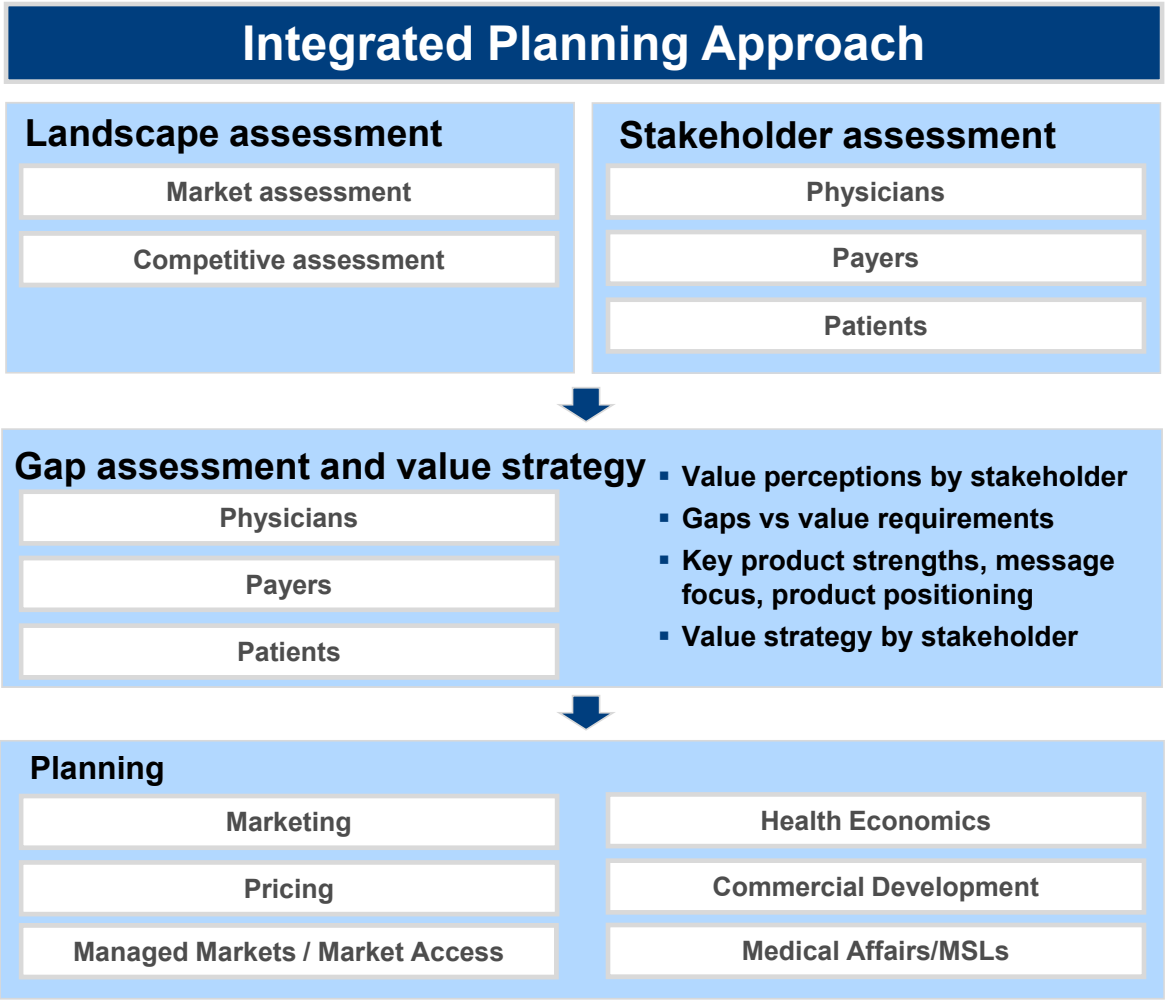
Typical Late-Phase Issues

- Optimal gross/net pricing
- Refined stakeholder value propositions, positioning, and messaging
- Post-marketing study planning
- Identification of resources required for launch (manufacturing, sales, etc.)

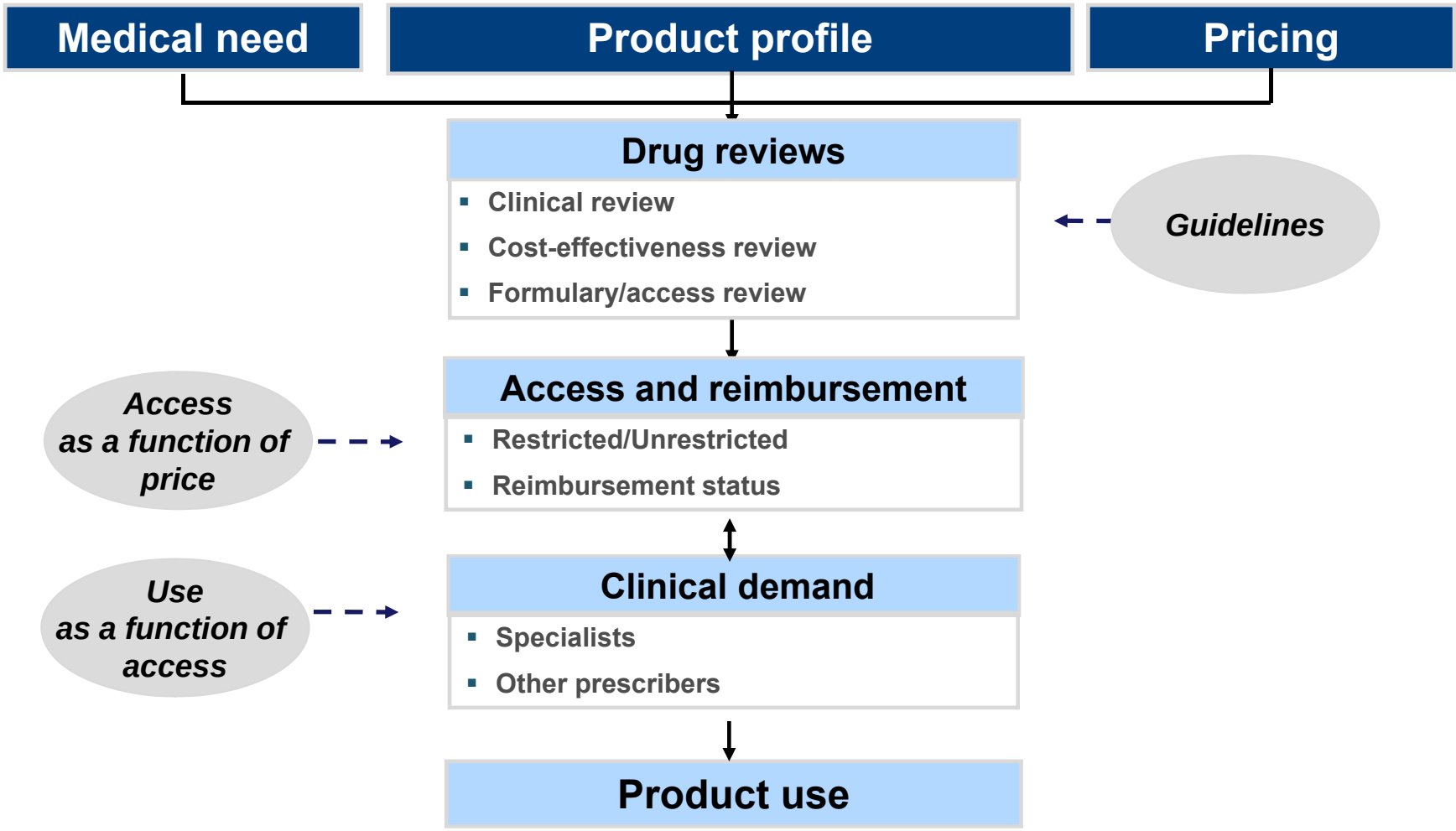
Value Planning and Payer Research

- Quantitative pricing analysis
- Market access and contracting strategy

Evidence based reimbursement and communication requires fully integrated planning



Later phase strategy for evidence based reimbursement focuses on payer decisions



General Approach to Planning for Evidence Based Reimbursement and Commercialization

Landscape and Stakeholder Assessment → **Gap Assessment and Value Strategy** → **Planning**

- ***Assess market landscape and stake-holder perspectives***
- ***Characterize context and performance requirements for successful product***

- ***Evaluate gaps between TPP, anticipated or available evidence, and stakeholder expectations***
- ***Set value objectives and strategy***

- ***Develop functional tactical plans, with defined accountability***
- ***Specify planned activities and deliverables to fulfill value strategy***

Case study:
Using payer research to inform clinical study design

Business challenge

How should a pivotal trial design be enhanced to respond to payers' needs for information about product value?

Key Issues

No understanding of how the market would perceive the new drug from clinical or economic perspectives

Several areas of uncertainty

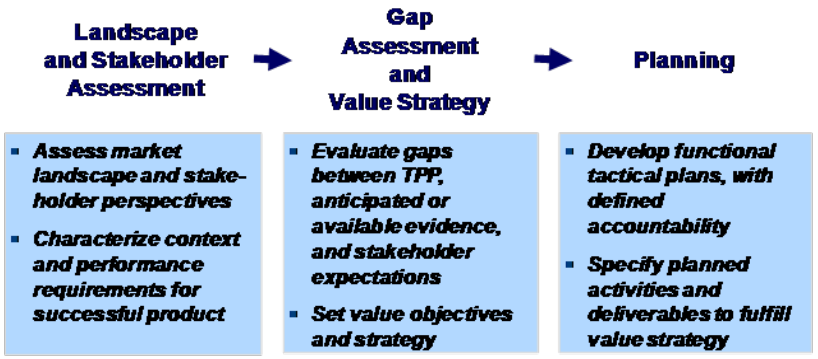
- **Potential range of clinical outcomes**
- **Degree of competition**
- **Likely access and reimbursement conditions at launch in the US and leading EU countries**

Objective: Develop an evidence-based plan for reimbursement and commercialization that integrated clinical, commercial, and economic perspectives

Approach included assessing landscape and payer perspectives, gap analysis and SWOT, and clinical program recommendations

Selected project objectives:

- **Understanding global market access issues** related to the likely product profile and attributes, given the current and potential future market competitors



- **Identifying key assumptions covering a range of possibilities at launch** for the product safety and efficacy profile, the competitive landscape, and the reimbursement environment

- **Developing recommendations for the value strategy,** with the ultimate objectives of ensuring preparedness to deliver key value messages and an overall value proposition for payers, given the desired product positioning, and supported with evidence

Case included both primary and secondary research

Secondary Research

- Identify information gaps to inform payer research

Articulate Alternative Product and Competitive Scenarios

- Define and refine product profile and competitive scenarios relevant to payers

Conduct Primary Payer Market Research and Assess Payers' Perceptions

- Product value drivers
- Perceived value of specific product attributes
- Relationship between product profile and market access expectations
- Determine implications for clinical study program

Develop Specific Recommendations for Evidence-based Value Strategy

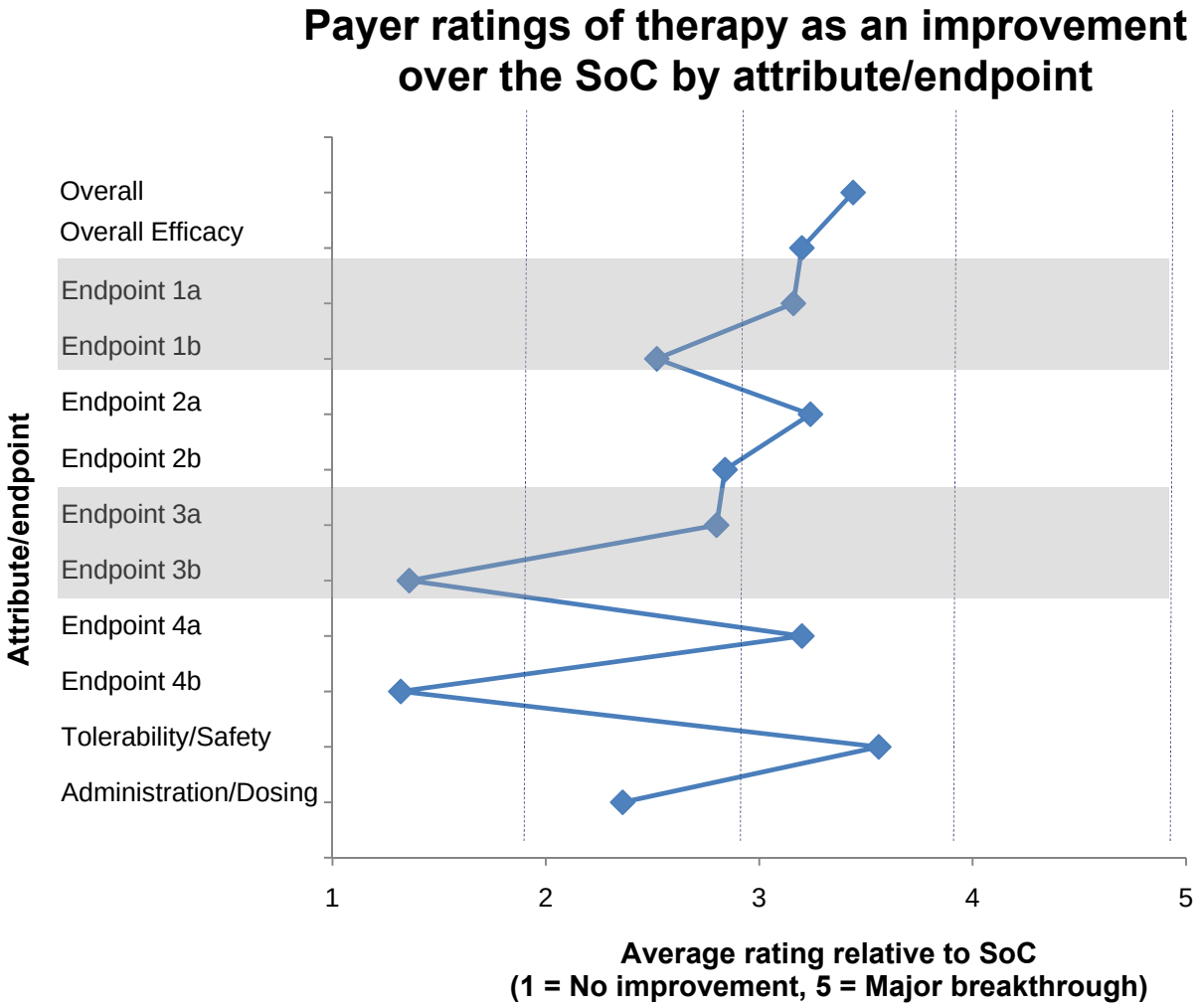
Payer research included questions about current therapies, payer management, and expectations for future therapies

Attribute	Question/Subtopic
Standard of Care and Unmet Needs	▪ Overall evaluation of current therapies ▪ Current and expected evolution of standard of care ▪ Satisfaction with standard of care by attribute
Access/Reimbursement Management	▪ Key criteria used to evaluate therapies for access/reimbursement ▪ Expected impact of generics on future access/reimbursement recommendations
Pipeline Therapies	▪ Clinical assessment of pipeline therapies ▪ Identification of desired clinical and economic evidence for pipeline therapies ▪ Identification of clinical endpoints and levels associated with relevant therapies

Payer research also included detailed questions about the TPP and expectations for access and reimbursement

Attribute	Question/Subtopic
Overall Assessment	▪ Rating as a therapeutic improvement over the standard of care
Mechanism of Action	▪ Potential benefits and drawbacks of the mechanism of action
Indication/Patient Population	▪ Impressions about use among different patient segments
Trial Design	▪ Impressions of the trial design, in terms of study arms, sample size, study population, length of treatment, and endpoints
Efficacy and Other Clinical Attributes	▪ Rating of overall efficacy compared to the standard of care ▪ Impact of overall efficacy on likelihood of achieving reimbursement/access with restrictions no more significant than today's standard of care ▪ Similar questions to efficacy were explored for more specific efficacy endpoints, tolerability/safety, administration/dosing, and budget impact
Reimbursement Recommendation	▪ Recommendation for reimbursement/access and restrictions ▪ Identification of reimbursement/access changes from base case under various efficacy scenarios

Payers viewed the profile for the therapy as a substantial improvement over current standard of care



Payer research also revealed that sources of value might differ by patient sub-group

Product Vision

Most effective and well tolerated treatment of mild to moderate symptoms in its class

↓

Preliminary Payer Value Proposition

Adjunct therapy with the SOC delays disease progression by safely and tolerably delivering longer/better efficacy than SOC alone, leading to reduced resource use and better quality of life

Potential Sources of Value to Payers

Sub-group 1

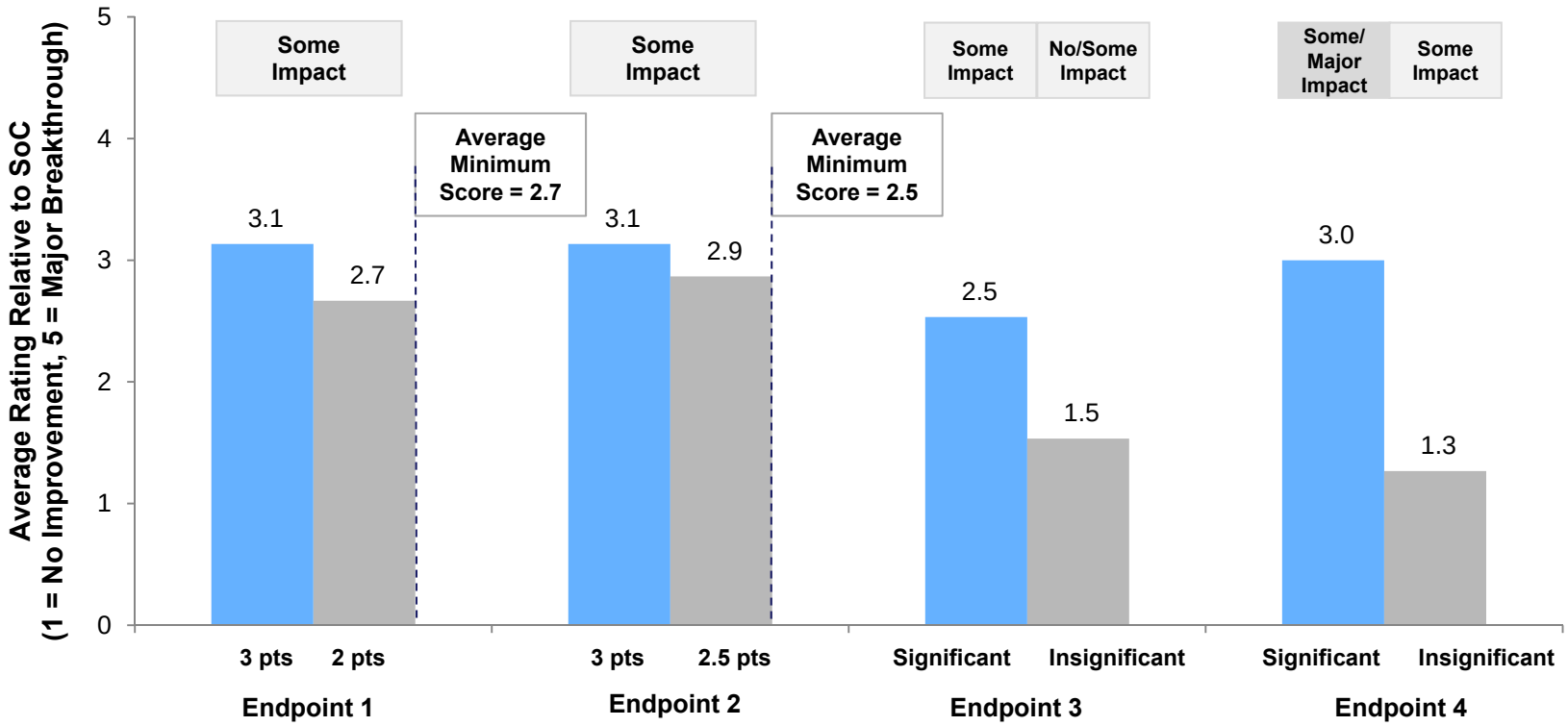
- ***Disease modification***
- **Safely and tolerably leads to greater efficacy**
- **Reduced patient medical treatment costs**

Sub-group 2

- ***Slowed disease progression***
- **Safely and tolerably leads to *delayed* symptoms**
- **Better patient quality of life**

Payers provided insight into likely market access given alternative product profile scenarios

Achieving no significant effect for endpoints 3 and 4 might significantly undermine access and increase restrictions for the therapy



Note: Boxes shown at the top of figure denote responses regarding to what extent each level of efficacy was expected to have on the therapy's positive formulary access/reimbursement review such that access/reimbursement with restrictions comparable to the today's standard of care would be achieved.

Payer research and its implications revealed strategic risks for which evidence generation strategies were developed

Strategic Risks	Risk Management and Evidence Generation Strategies
Potential definition and realization of "disease modification" are highly uncertain	▪ Educate payers (and physicians) to establish place of product in therapy ▪ Modify value proposition for each sub-group
Highly competitive landscape for novel therapies with disease modifying properties possible at launch	▪ Develop early phase economic modeling ▪ Continually reassess potential value proposition based on new data
Disease modification may be demonstrated only in certain sub-groups	▪ Enhance evidence base with real-world analyses stratified by subgroup and focusing on burden of disease
State of biomarker validation and acceptance will be a challenge	▪ Monitor biomarker development and consider appropriate investment opportunities

Analogue assessments provide a wealth of information to inform planning for evidence based review

Several organizations conduct reviews of evidence to inform clinical guidelines and reimbursement decisions

	Selected Examples	
	US	**Ex-US**
Health Technology Assessment	▪ CMS sponsored NCA may include request for HTA from AHRQ ▪ BC TEC	▪ UK NHS—NICE TA ▪ UK SMC ▪ Australia—PBAC
Systematic Review	▪ AHRQ	▪ Canadian provincial reviews
Professional Society Guidelines (examples)	▪ NCCN ▪ ADA ▪ AACE*	▪ ESMO ▪ EASD**
Coverage Decisions	▪ Aetna, Cigna, Humana, Blues ▪ CMS NCA/NCD	▪ Canadian national and provincial reviews ▪ France—HAS ▪ Germany—IQWiG

*American Association of Clinical Endocrinologists **European Association for the Study of Diabetes

For example, an analogue assessment for a new diabetes product in development would be based on several sources

	US	Ex-US
Health Technology Assessment	▪ **AHRQ** Technology Assessment: Applicability of the Evidence Regarding Intensive Glycemic Control and Self-Monitored Blood Glucose to Medicare Patients with Type 2 Diabetes (9/10/2007)	▪ **NICE** TA53: Diabetes (types 1 and 2) - long acting insulin analogues: guidance (Dec. 2002) ▪ PBAC Public Summary Document: Exenatide (Nov. 2008)
Systematic Review	▪ **AHRQ** EPC Evidence Report: Comparative Effectiveness and Safety of Oral Diabetes Medications for Adults With Type 2 Diabetes (7/16/2007)	▪ **Ontario Ministry of Health & Long-Term Care**: Insulin Glargine (3/2009)
Professional Society Guidelines	▪ **AACE**: Medical Guidelines for Clinical Practice for the Management of Diabetes Mellitus (2007)	▪ **EASD:** Guidelines on diabetes, pre-diabetes, and cardiovascular disease (2007)
Coverage Decisions	▪ **Aetna:** Pharmacy Clinical Policy Bulletins, Non-Medicare Prescription Drug Plan: Insulins (2/12/2010)	▪ **HAS** Transparency Committee Opinion: Lantus (1/21/09) ▪ **IQWiG**: Long-acting insulin analogues in the treatment of diabetes mellitus type 1 (2/18/2010)

Assessing market factors and strength of evidence for relevant analogues informs market access risk

Market Factors

Therapeutic Area	Drug	Market Factors: Number of patients (budget impact)	Market Factors: Availability of multiple efficacious substitutes	Market Factors: Availability of substitutes with the same MOA	External Challenge
A	1	●	◔	◔	◑
	2				
	3				
B	4				
	5				
B	1				
	2				
C	6				
	7				
	8				
	1				
	9				
	10				

○ = 0 ◔ =1 ◑ =2

Product Attributes

Therapeutic Area	Drug	Product Attributes: Efficacy (OS, PFS, Response, Sx QOL)	Product Attributes: Safety	Product Attributes: Cost-Effectiveness	Strength of Evidence
A	1	◑	◑	◑	◑
	2				
	3				
B	4				
	5				
B	1				
	2				
C	6				
	7				
	8				
	1				
	9				
	10				

○ = 0 ◔ =1 ◑ =2

Market Factors

- Number of patients/budget Impact
- Availability of multiple efficacious substitutes
- Availability of substitutes with the same MOA

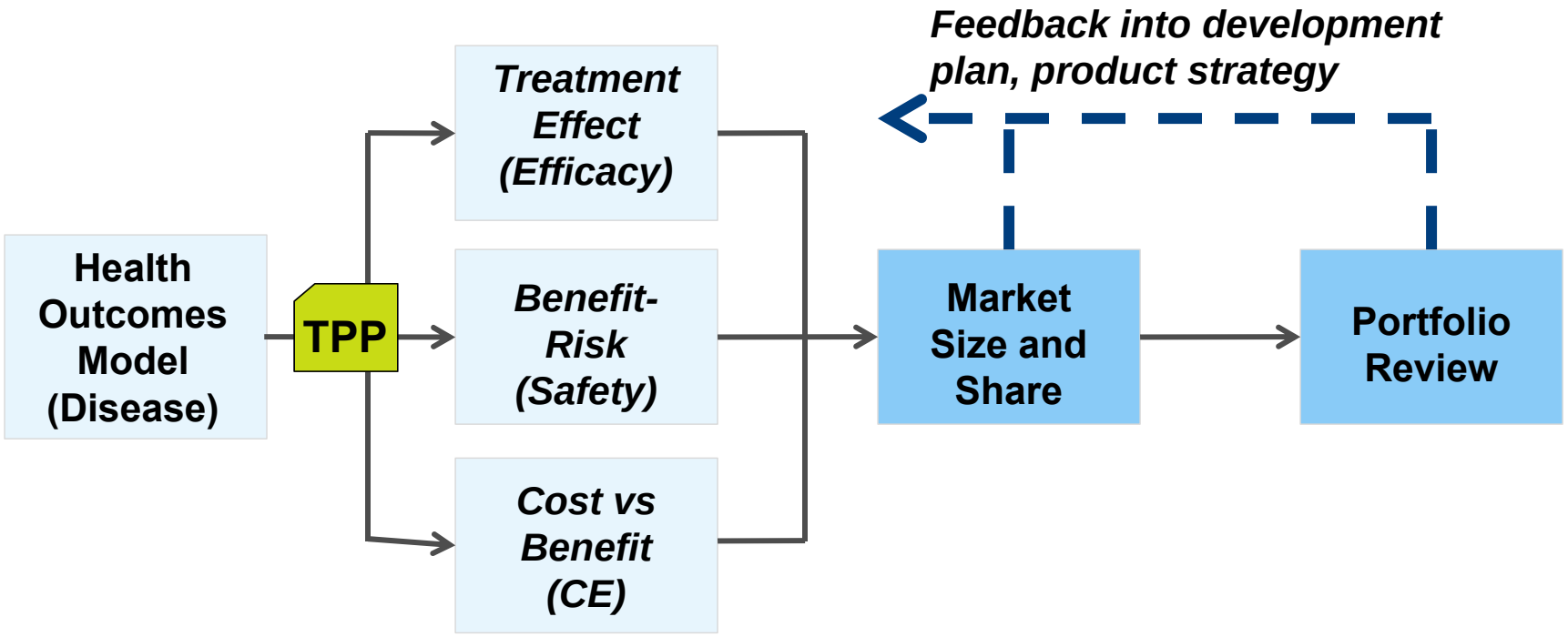
Intensity of External Challenge

Product Attributes

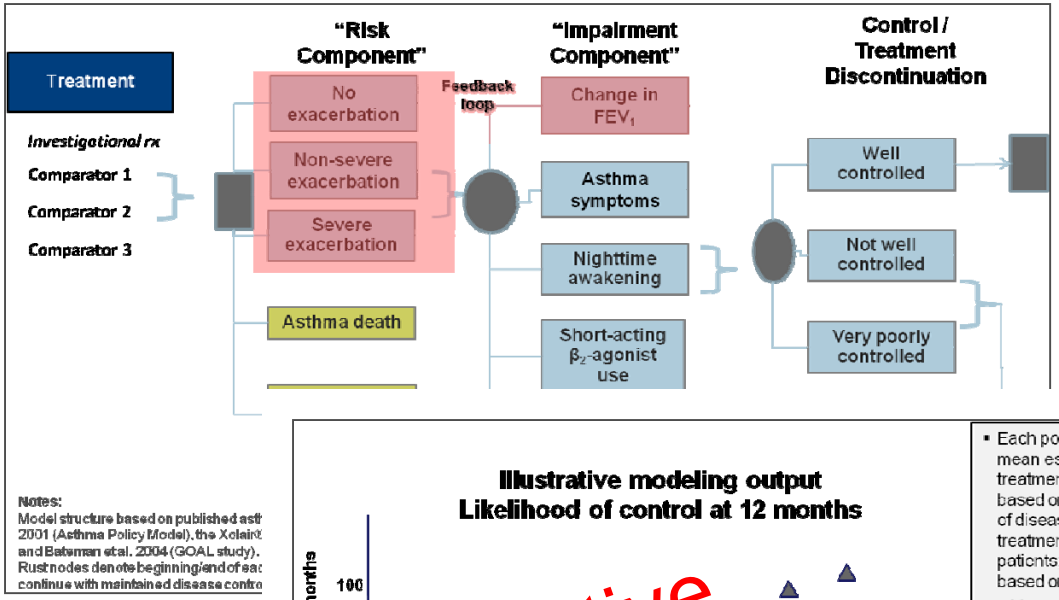
- Efficacy
- Safety
- Cost effectiveness

Assessments of market access risk informs strategic planning for evidence based reimbursement and commercialization

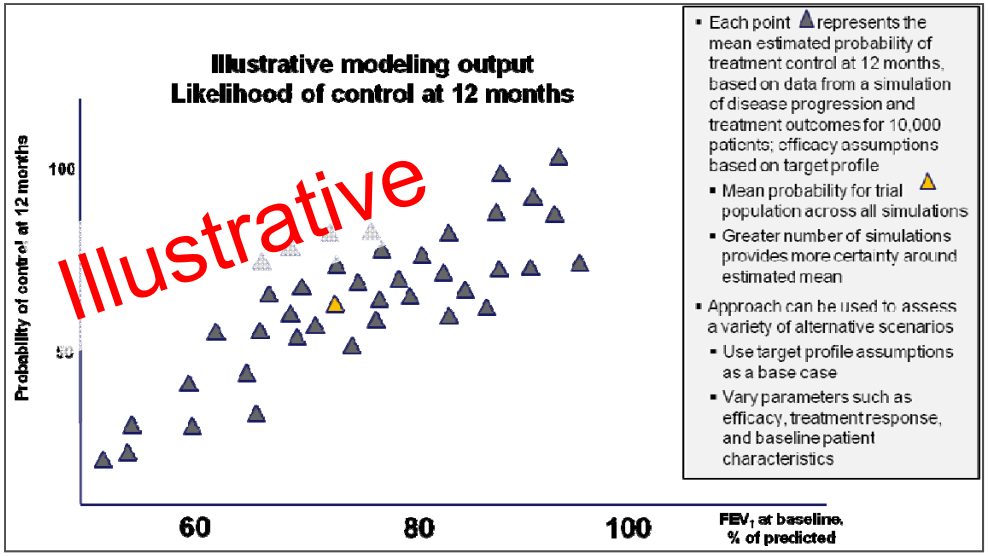
Early-phase simulation modeling of likely product scenarios also informs evaluation of potential strength of evidence



Example: Early-phase health outcomes modeling in asthma



Schematic representation of simulation model



Sample output

Summary

The environment today and in the future presents new challenges

- Evidence for regulatory approval is no longer sufficient for optimizing market access and product uptake

These challenges create an imperative for a different approach to developing pharmaceutical and biotechnology products

- Strong evidence of product value, from multiple perspectives, is critical for successful market access and commercialization

Pharmaceutical and biotechnology companies, as well as investors, must assess critically the strength of evidence and opportunities to enhance the evidence base as product are developed—product value will depend on it

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