WHIS

WHAT PAYERS DON'T KNOW COULD HURT YOU

How to navigate pre-launch payer engagement as a women's health drug developer

Kisaco Research

GOOD SCIENCE ISN'T ENOUGH

There is a moment in every promising therapy's journey when clinical success and commercial failure become equally possible. The science works. The unmet need is real, and yet, between a positive trial result and a woman actually receiving treatment, something goes wrong.

That something is not always clinical. It is often the ecosystem surrounding it, specifically the relationship between innovators and the payers who control access to the patients they are trying to reach.

WHIS wants to close that knowledge gap. This report distils the insights from one of the most practically valuable sessions at the 2025 summit: a candid, unfiltered conversation with Jim Kenney, who spent 38 years on the other side of the table at Harvard Pilgrim Health Care, negotiating the agreements that determine whether drugs get covered, restricted, or quietly buried under prior authorization requirements most patients never overcome.

What he described should change how every women's health innovator thinks about commercial strategy.

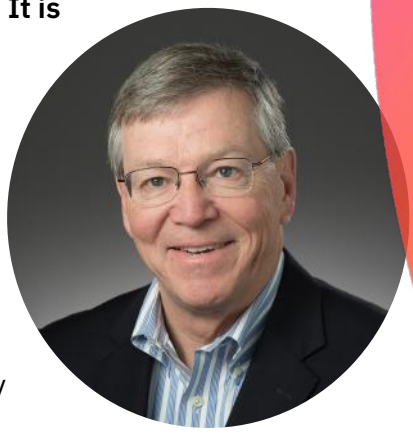
Poppy Howard-Wall
Lead Producer
Women's Health Innovation Summit

Why Payer Engagement Is the Missing Piece

When a payer encounters a new product for the first time on the day it launches, the outcome is almost entirely predictable. They may not know the drug or the manufacturer, especially for rare diseases, and absent good information about the product, they cannot be sure where it fits. In many cases, this leads to restriction.

Prior authorization requirements are added. Step-edit mandates are imposed. The drug lands on a formulary tier that makes it effectively inaccessible to many of the patients who need it most. And here is the part that most innovators do not fully appreciate: once those restrictions are in place, they are extremely difficult to remove. Medicare does not permit negative formulary changes mid-cycle. What gets built at launch tends to stay.

The solution is not better post-launch sales activity. It is not a more compelling medical affairs team. It is structured, transparent engagement with payers that begins long before a product ever reaches the market.



Jim Kenney

To unpack what that looks like in practice, WHIS convened Jim Kenney, founder of JT Kenney LLC and a 38-year veteran of Harvard Pilgrim Health Care, where he led formulary management, pharmacy

and therapeutics committee oversight, and negotiated outcomes-based agreements across virtually every disease category. What follows is what the industry rarely hears: the payer's perspective, spoken plainly.

Tool #1: Pre-Approval Information Exchange (PIE)

For much of the industry's history, manufacturers operated on the assumption that sharing clinical data with payers before approval was a risk. Give them too much information, the thinking went, and they will use it to build restrictive utilization management criteria before the product ever reaches market.

Kenney's view, developed over nearly four decades of sitting on the other side of that conversation, is the opposite. The manufacturers who held back information were not protecting themselves. They were guaranteeing the outcome they feared.

The Pre-Approval Information Exchange framework — PIE, developed by the Academy of Managed Care Pharmacy — exists to make that early sharing structured, compliant, and genuinely useful. It creates a formal channel through which manufacturers can share clinical and health-economic data with formulary decision-makers ahead of FDA approval. It is not a marketing channel. It cannot be used to negotiate contracts. What it can do is ensure that when a payer encounters a product at launch, they are not encountering it for the first time.

Used well, PIE allows manufacturers to walk payers through the disease landscape and unmet need, share clinical endpoints and safety data, outline post-launch monitoring plans, and begin building the kind of mutual understanding that determines whether a launch goes smoothly or not. The AMCP dossier format provides a standardised structure that many health plans use as their primary reference for formulary decisions.

On timing: most payers want to begin engaging six to twelve months ahead of the PDUFA date. For high-cost or high-impact categories — the kind that send formulary teams into emergency planning mode — earlier is better.

FACT BOX: WHAT PIE CAN AND CAN'T BE USED FOR

PIE allows manufacturers to share: disease background and unmet need, clinical trial endpoints and safety data, early health-economic models, risk management requirements, and post-launch monitoring plans.

PIE cannot be used for: promotion or early marketing to providers, direct price negotiations, or broad commercial outreach beyond clinical and formulary decision-makers.

For the full PIE framework, visit amcp.org

CASE STUDY: THE COST OF GETTING PATIENT NUMBERS WRONG

When Vertex launched Kalydeco (ivacaftor) for cystic fibrosis, priced at around $280,000 per year, the manufacturer projected approximately 40 patients at one health plan. The actual figure was 62, representing roughly $10 million in unbudgeted spend.

THE LESSON
If you think a plan might see 100 patients, tell them 120. A pleasant surprise is far easier to manage than an unpleasant one.

One point Kenney was emphatic about: do not underestimate your patient population projections. Payers build their budgets around these figures. They work with actuaries. An underestimate does not just cause administrative inconvenience — it damages the relationship at precisely the moment when you need it most.

Tool #2: PDUFA Timelines as an Engagement Anchor

The PDUFA date — the FDA's target deadline for an approval decision — is not just a regulatory milestone. For payers, it is the clock their entire coverage planning process runs against. For manufacturers, it should function as the anchor point for every engagement decision in the commercial calendar.

Three to six months out, when approval confidence is high, is when outreach should intensify: finalizing coverage materials, aligning on utilization management criteria, and resolving the question that derails more launches than almost any other — distribution.

Distribution is the element of launch readiness that receives the least attention and causes the most damage. It is particularly acute for high-cost therapies administered through the medical benefit, where providers are being asked to

CASE STUDY: HEMGENIX — A CAUTIONARY TALE ON DISTRIBUTION

Hemgenix, the gene therapy for haemophilia B, was approved in late 2022 but did not reach its first patient until the following June, a gap of nearly seven months. The reason was distribution. At $3.5 million per treatment, providers needed confidence they would be reimbursed before committing capital. That confidence had not been established.

For women's health innovators working on high-cost or complex-administration therapies: your pharmacy or administration partner needs to be contracted, networked, and ready to operate on day one. A covered drug that cannot reach patients is still a failed launch.

purchase and administer a product before reimbursement is confirmed. At that price point, confidence in the payment pathway is not a nice-to-have. It is a prerequisite for the drug ever reaching a patient.

Solve distribution before launch, not after. A drug that is covered but cannot be administered is not a successful launch. It is a covered failure.

Tool #3: Outcomes-Based Contracting

For high-cost therapies — and women's health is producing more of them — the question payers are really asking is not whether the drug works in a clinical trial. It is whether it will work in their population, over the time horizon that matters to their budget, and whether someone will share the risk with them if it does not.

Outcomes-based contracting is the answer to that question. Rather than asking a payer to absorb full financial exposure on the basis of trial data alone, the manufacturer puts performance-based terms on the table: if the product delivers the outcomes it promises, the payer pays. If it does not, the risk is shared.

Kenney negotiated approximately thirty such agreements during his time at Harvard Pilgrim, across virtually every disease category. His experience makes clear that they work — but only when three conditions are met.

Endpoints must be within the approved label. A manufacturer cannot contract on an outcome the drug is not indicated for, however compelling the supporting evidence.

Outcomes must be measurable from claims data — most payers do not have access to electronic health records. And transparency about data gaps is not a weakness to be concealed — it is an invitation to collaborate. A payer who understands what you do not yet know about durability or long-term safety is a far more constructive partner than one left to assume the worst.

CASE STUDY: ONPATTRO AND ALNYLAM — GETTING IT RIGHT

Alnylam began structured engagement with Harvard Pilgrim Health Care a full year before Onpattro's PDUFA date. By approval, both parties had worked through the clinical evidence, the target population, and a value-based framework. Within three months of launch, the drug was covered, utilization management criteria were agreed, and patients had access.

The contrast with a cold launch, where a payer encounters a novel high-cost therapy for the first time at approval and responds with maximum restrictions, could not be starker.

Practical Pitfalls to Avoid

Two patterns reliably undermine launches that should succeed.

The first is leading with convenience rather than clinical value. A new dosing form, a more favourable administration route, a simplified regimen — these matter to patients and providers, and they are worth communicating. But payers will not grant preferential formulary placement on that basis alone. If convenience is the headline of your value story, payers will wonder what is missing from the clinical story underneath it. Lead with the outcome data. Let convenience be the supporting argument.

The second is neglecting the prior authorization design process. The criteria that determine whether a patient can access a drug are often written without the manufacturer's input and may include requirements that are clinically unjustifiable, operationally unworkable, or simply wrong.

When Sarepta reviewed Harvard Pilgrim's draft prior authorization criteria for Exondys 51 in Duchenne muscular dystrophy, they flagged that a muscle biopsy requirement had no precedent at any other plan in the country. That feedback led to the requirement being removed. That kind of correction only happens when the relationship is strong enough to support honesty in both directions — and that relationship only exists if engagement began early.

What This Means for Women's Health Innovators

The conditions being addressed by women's health innovators: endometriosis, menopause, maternal health, rare gynaecological conditions, share a structural characteristic that makes payer engagement both more difficult and more important than in established therapeutic categories.

Payers have limited comparators. Evidence bases are thinner. The established treatment landscape that would normally anchor a coverage conversation often does not exist.

That is not an obstacle. It is an opportunity. When a payer has no precedent to draw on, the manufacturer who shows up early, shares data openly, and proposes a credible outcomes framework has an outsized ability to shape how their product is understood and managed. In a category where the default is uncertainty, preparation is a competitive advantage.

Five Takeaways

The companies that successfully convert clinical promise into patient access share a common characteristic. They do not treat payer engagement as a commercial task that begins at approval. They treat it as a scientific and strategic relationship that begins years earlier — and they invest in it accordingly.

1. Start early.

Six to twelve months before your PDUFA date is the minimum. For high-cost or high-impact products, earlier is better. The relationship you build before approval is the one that determines what happens after it.

2. Use PIE to create genuine understanding, not just awareness.

A payer who has seen your disease burden data, your clinical endpoints, and your population projections is a different kind of partner than one encountering your drug cold. Build the understanding, not just the awareness.

3. Solve distribution before launch.

A covered drug that cannot reach patients is a failed launch. Your pharmacy or administration partner needs to be contracted, networked, and ready before day one.

4. Design for outcomes measurement from the start.

Confirm your endpoints are within the approved label and trackable from claims data. If you cannot measure it from a claims system, you cannot contract on it.

5. Be transparent about what you do not know.

Durability data is incomplete. Long-term safety is still emerging. Payers who understand your uncertainties will work with you to monitor them. Payers who are left to assume the worst will protect themselves accordingly — and so will their patients.

About WHIS

The Women's Health Innovation Summit (WHIS) is the leading event for the women's health ecosystem, bringing together innovators, investors, payers, and providers to share insight and accelerate progress in one of the most important sectors in healthcare.

WHIS 2026 is coming. Join the waitlist today.

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