

Satisfaction Guaranteed

Or Your Money Back

BY BOB CARLSON, MHA, Senior Contributing Editor

The term *risk sharing* is sometimes tossed around when, technically, there's little or no financial risk involved. One such deal made a big splash in April when Merck & Co. and Cigna announced a discount agreement for sitagliptin (Januvia) and the sitagliptin phosphate/metformin hydrochloride combination (Janumet), Merck's new oral medications for type 2 diabetes.¹

Merck agreed to increase the discounts it offers Cigna on Januvia and Janumet if hemoglobin A_{1c} values for Cigna enrollees on *any* oral diabetes medications improve by the end of the year. Even bigger discounts will come Cigna's way if its claims data show that these enrollees have actually been taking their medications as prescribed. Cigna is encouraging its customers to avail themselves of its medication adherence programs to make that happen.

"Merck should be recognized as the first major pharmaceutical company to offer increased discounts on its oral anti-diabetic products, supporting Cigna's efforts to reduce A_{1c} levels for individuals with

diabetes, regardless of what medication they may be taking," said Eric Elliott, president of Cigna Pharmacy Management in the April news release. "Improving people's health comes first for both Cigna and Merck. We hope this agreement will become a model in the industry."

Merck expects that incremental utilization of diabetic medicines by Cigna enrollees will generate at least its market share of Januvia and Janumet sales, and that the health status of Cigna members with type 2 diabetes will improve. Not incidentally, the deal also gave Merck big-payer access before competing dipeptidyl peptidase-4 (DPP-4) inhibitors hit the market.

"We believe that this is a positive way to work for better healthcare outcomes for patients," says David Hartenbaum, senior director of health plan contracting at Merck. "I

think it's a great partnership between Merck and Cigna, because we're both aligned and working in the same direction. Now we need to wait and see what the outcomes are."

Hartenbaum says Merck is "in preliminary discussions" about similar contracts with other payers, but declined to elaborate.

News of Merck's and Cigna's performance-based contract actually came a few days after a different announcement of another agreement — a classic financial risk-sharing deal. Proctor & Gamble Pharmaceuticals and partner sanofi-aventis committed to reimbursing Urbana, Ill.-based Health Alliance Medical Plans with rebates and discounts for the medical costs of osteoporosis-related nonspinal fractures in postmenopausal women taking P&G's osteoporosis drug risedronate (Actonel).²

¹ Cigna and Merck Sign Performance-Based Contract [press release]. April 23, 2009. <http://newsroom.cigna.com/article_display.cfm?article_id=1043>. Accessed Oct. 8, 2009.

The pitch is as American as Mom and apple pie, and some biotechs and pharmaceutical companies are using it – or something similar – in their contracts with payers. Although more common in Europe, these so-called ‘risk-sharing contracts’ are attracting renewed interest in the United States.

STANDING BEHIND THE DRUG

These two heavily hyped contracts may be the wave of the future, but if you’ve been in the healthcare business for a while, you may remember that sharing risk was a big deal back in the 1990s.

“Risk sharing in general has ebbed and flowed,” notes Bruce Pyenson, FSA, MAAA, principal and consulting actuary with Milliman Inc., the actuarial consultancy.

“In the 1990s, we saw physicians and hospitals taking risk in the form of capitation and other kinds of arrangements. Some of those survived, many of them did not. Ultimately, the market decided that it was willing to pay more money for doing business the usual way. We’re now at a point where that may be unsustainable.”

That’s one reason why risk-sharing contracts between pharmaceutical companies and payers have been attracting interest in the United States. Pharmaceutical companies that do business here also do business in Europe, where risk-sharing

arrangements and other innovative contracts with payers are much more common. So some of the renewed interest here is undoubtedly spillover from abroad.

For example, Novartis has inked risk-sharing pilot programs with the National Health Service in the United Kingdom for its biologic therapy to treat age-related macular degeneration, ranibizumab (Lucentis); with two public health insurances within the German health care coverage system for its injectable drug for osteoporosis, zoledronic acid (Reclast); and with an unnamed health plan in the United States for an antihypertensive agent, valsartan (Diovan).

“We’re piloting a number of them, in Europe

primarily but we also are now beginning to [do so] in the United States,” says Joe Jimenez, CEO of Novartis Pharmaceuticals in Basel, Switzerland. “Italy is very interested in these deals, as is Sweden, because Sweden has a NICE-like agency.”

In the United Kingdom, the National Institute for Health and Clinical Excellence (NICE) has become a model for other national health technology assessment agencies. Getting the nod from NICE often means first negotiating a creative risk-sharing deal with the Department of Health. For its ranibizumab

pilot program, Novartis has made an agreement with the UK’s National Health Service to provide eye injections at no cost for a patient after that patient has received 14 injections in each eye.

“That’s standing behind the drug,” declares Jimenez. “Lucentis is a real breakthrough drug that we know is effective, and if a patient is getting that many injections, then we’re willing to cover the cost after the 14th injection. This is a cost-effective way for us to get Lucentis to patients.”

Two of Germany’s so-called sickness funds signed off on Reclast after Novartis agreed to refund the cost of the osteoporosis drug if a patient on the drug has a fracture. Jimenez notes that Reclast is infused once annually, virtually guaranteeing 12 months of medication compliance.

The key to a successful risk-sharing contract, Jimenez believes, is a drug that fills an unmet medical need and makes a major difference.

“Regulators don’t want to approve therapies that are only incrementally better, and payers don’t want to pay for them,” Jimenez explains. “So, we’re shifting toward filling those big areas of unmet medical need and standing behind the drug and offering value beyond just the medicine itself. That’s where we see these so-called risk-sharing contracts. We think of them more as outcomes-based contracts with payers.”

According to NICE, recent risk-



“Risk sharing is one way to raise a barrier to your competitors,” says Bruce Pyenson, principal and consulting actuary with Milliman Inc.

² Health Alliance Announces First Fracture Protection Program for Actonel [press release]. April 14, 2009. <<http://www.reuters.com/article/pressRelease/idUS154895+14-Apr-2009+PRN20090414>>. Accessed Oct. 8, 2009.

sharing agreements negotiated with the UK Department of Health also include Celgene's lenalidomide (Revlimid), Roche/Genentech's erlotinib (Tarceva), Eyetech and Pfizer's pegaptanib (Macugen), Millennium Pharmaceuticals' and Johnson & Johnson's bortezomib (Velcade), and Pfizer's sunitinib (Sutent).

WHERE YOUR MOUTH IS

"Because of cost pressures, payers want manufacturers to have more skin in the game," says Kate Fitch, RN, MEd, principal and healthcare management consultant at Milliman, who works with Pyenson on structuring risk-sharing deals for pharmaceutical companies and payers. "For pharmaceuticals, that means putting your money where your mouth is."

Exactly how to do that is where a growing army of consultants, pricing advisors, lawyers, and actuaries comes in. Pyenson is in the latter category and has been advising clients in the United States and abroad on risk-sharing arrangements since before their first iteration in the 1990s. He describes the current iteration of risk-sharing contracts as "exploratory."

"When we go into a project and learn about the particular issues a payer or manufacturer is facing, we often can find models from across the spectrum of actuarial science that seem to come up with a solution for both the buyer and seller," says Pyenson. "Some of them, depending on the characteristics of the disease and the product, fit very, very well."

The heavy lifting involves figuring out what a pharma client should put at risk and whether that risk entails clinical outcomes or cost reductions, analyzing claims data to identify and quantify target popula-



"Where risk-sharing arrangements are targeted and where you can stand behind the medicine as not just incrementally better but significantly better ... that is a win-win situation," says Novartis CEO Joe Jimenez.

tions (such as people with diabetes or women with osteoporosis), determining typical utilization patterns, and modeling the cost impact of the drug and the disease state cost burdens — all which are what Fitch does.

"It's bringing together the analytics and the clinical story," is how Pyenson sums it up. He declined to name clients, explaining that "risk sharing is one way to raise a barrier to your competitors."

The challenge for pharmaceutical companies, in Pyenson's view, is that insurance companies "do" risk as a business, whereas pharmaceutical manufacturers and biotechs do drug discovery and development. In other words, most biopharma companies are novices when it comes to risk-sharing contracts.

"Payers are used to making risk arrangements for behavioral health, laboratory services, and other services that they buy," he says. "Radiology carve-outs, for example, are another category that's growing."

That may be, but not all payers think or act alike.

"Payers have different levels of interest in risk sharing," Pyenson acknowledges. "Some are more inclined to experiment."

Nor do payers necessarily have the information technology infrastructure that would readily identify the right patient population, contact the right physicians, and capture the relevant data in a particular risk-sharing scenario.

"A health plan has to be truly motivated to execute the type of contract we have with Cigna," says

Merck's Hartenbaum. "We have had plans contact us after reading the Cigna press release, and when they find out what they have to do, it's like 'We're not interested,' 'We don't have the infrastructure,' 'We don't have the time,' or 'We just don't feel we can do it.'"

For the most part, neither payers nor pharmaceutical companies are all that keen to try this new approach to contracting, at least not in the United States. That's been Rob Glik's experience as senior principal, pricing & market access at IMS Health, which provides global market intelligence to the pharmaceutical and healthcare industries. He estimates that about half of all global risk-sharing contracts are performance based and half are financial, and that two thirds are for small-molecule products and one third for biologics.

"Risk-share agreements definitely have increased in popularity over the last four to five years in Asia and Europe," says Glik. "In the United States, we've seen more interest in the last one to two years."

The reason for the disparity, Glik believes, is that drug makers still have relatively good access to the U.S. market (i.e., to payers). That's not true in Europe, where national single payers are subject to greater budgetary constraints and also wield more bargaining clout.

In fact, the UK's Department of Health and NICE may be where risk-sharing schemes as we know them today got their start, according to Nicholas Keppeler, a director with the global strategy and marketing firm Simon-Kucher & Partners, which provides strategy and marketing advice to the life sciences industries.

"One of the first areas where we saw risk-sharing contracts was in the United Kingdom," recalls Keppeler,

who is based in Simon-Kucher & Partners' office in Cambridge, Mass. "Manufacturers found that this was a good way to make the costs per quality-adjusted life year (cost per QALY) for a product acceptable to NICE without sacrificing the list price of the product — which is important in fighting threats such as international reference pricing and parallel trade in an open EU market."

But even within Europe, risk sharing has caught on more in some countries than in others. Christian Schuler, a partner in Simon-Kucher & Partners' life sciences division, works with Bay Area pharmaceuti-

Sharing risk can be beneficial for all parties, enabling the pharmaceutical and biotechnology companies to enter new markets, make new therapies available to more patients, and provide payers with downside protection when medications don't perform as advertised.

cal and biotechnology companies out of Simon-Kucher & Partners' San Francisco office.

"The United Kingdom and Italy are the most advanced when it comes to risk-sharing agreements," Schuler says. "They are still under discussion in Spain. In France, we have secret price-volume agreements with CEPS [Comité Économique des Produits de Santé, the national agency responsible for drugs and medical devices]. In Germany, we have some examples of risk sharing, but on a regional or individual sick fund level — not on a national level."

After nine years in the Bonn office and two years in the Bay Area, Schuler still sees "question marks" about risk-sharing contracts in Eu-

rope and "even bigger question marks" in the U.S. market.

"We actually have not seen many risk-sharing agreements in the States," Schuler says. He characterizes pharmaceutical risk sharing in the United States as "an emerging trend" that faces significant barriers to implementation because of such U.S. market characteristics as the multipayer system with various stakeholders, the high demands it poses to the technology infrastructure, and challenges in finding the right deal structure.

"There has to be a strategic fit for risk sharing in the United States," says Schuler — "the right

product with the right offering for the right partner."

CHALLENGES ON VALUE

Is this the early phase of a boom in risk-sharing contracts in the United States? Or will the current stateside buzz fizzle out, as it did in the 1990s?

Several trends seem to support boom, not bust.

First, almost everyone interviewed for this article mentioned healthcare reform in the United States. Whatever comes out of Washington's legislative sausage grinder, the economic imperatives for reduced healthcare spending and increased quality are not likely to disappear.

“If they weren’t substantially higher priced, they would not be a challenge,” says Pyenson, referring specifically to biologics. “With well over 16 percent of the gross domestic product going to healthcare, which is unsustainable, anybody in the business of healthcare should expect challenges on what value they bring.”

Second, the mistrust generated by the abortive risk-sharing episodes of the 1990s seems to be abating.

“I have heard from insurers in the United States over and over again that 10 to 15 years ago there were quite a few risk-sharing pilot programs with big pharma, but they did not wind up being win-win situations,” says Glik. “Most of them ended up benefitting the insurer, not the manufacturer, so the manufacturer either did not renew the risk-sharing agreement or tried to break the agreement, causing mistrust between insurers and manufacturers regarding risk-sharing agreements. Only recently — mostly because they’ve been implemented successfully in Europe — are we starting to see a few more in the United States.”

Third, at its March meeting, the Medicare Payment Advisory Commission (MedPAC) discussed pharmaceutical risk-sharing contracts. Though it made no policy recommendations, the fact that MedPAC has addressed the topic is enough to get stakeholders’ attention.

Finally — and importantly — single-payer systems in Europe and elsewhere are likely to continue demonstrating that risk sharing can be a “win” for pharmaceutical companies, for payers, and for patients.

“There are not enough data yet to suggest that these kinds of arrangements should be very broad scale,

Types of pharmaceutical risk-sharing contracts

Return on investment, in terms of reducing overall healthcare costs, may be a gold standard for risk-sharing contracts, but ROI is difficult for biopharma companies to demonstrate. Nonetheless, say Bruce Pyenson and Kate Fitch, of Milliman Inc., meaningful risk-sharing deals can take a number of forms, depending on the product and population:

- Traditional capitation
- Managing orphan drugs
- Hold harmless for inappropriate use
- Clinical outcomes
- Refunds for adverse events

but where they’re targeted and where you can stand behind the medicine as not just incrementally better, but significantly better — as we’ve proven already in Europe — that is a win-win situation,” says Jimenez. “The Reclast agreement in Germany is a great example.”

Jimenez is obviously bullish about the prospects for risk sharing, but actually envisions a scenario in which risk sharing is less an end in itself and more of a waypoint in an industry-wide transition from simply flogging medications to promoting positive clinical outcomes. He sees his ramped-up in-house health economics team making the case to payers — not so much for risk sharing, but for downstream cost avoidance as a result of improved patient compliance and better outcomes.

“I think it’s going to be less about risk sharing and more about a holistic approach where the pharmaceutical company and the payer work together to help ensure positive outcomes for a patient population, because that’s really what they’re after,” says Jimenez. “The pharmaceutical industry can bring to the payer knowledge about what drives a patient to not comply with medications and programs that can help them comply, Jimenez adds. “Adherence programs have been

around forever, but I’m talking about taking a new approach.”

The new approach Jimenez refers to is proprietary research by Novartis on barriers to medication compliance. Novartis intends to marry its research with the development of new technology that involves embedded microscopic radio frequency identification chips that monitor if a medication is being taken as prescribed.

A LAST RESORT

Whether risk sharing turns out to be a step along the way or the “next big thing,” what it’s not is a panacea for pharmaceutical and biotechnology companies. It’s not even a preferred option, but a last resort.

“Risk-share agreements are gaining popularity mainly because of budgetary constraints by payers and the high cost of pharmaceuticals and biologics, so both sides are looking at alternatives when traditional contracting may not work,” says Glik. “Rarely is a risk-share agreement a manufacturer’s first line of defense in negotiating with a payer, but it could be the difference between getting reimbursement and good access or not.”

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