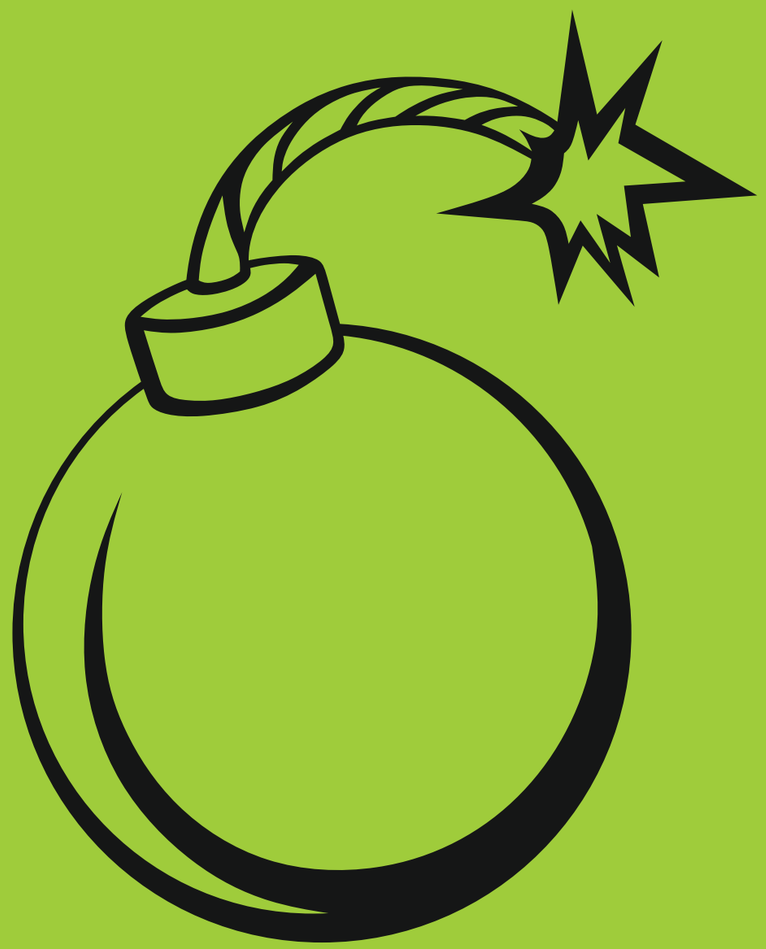

Formulary Fireworks

In the wake of the high-profile showdown between Gilead and Express Scripts over the pricing of hepatitis-C drugs Sovaldi and Harvoni, the pharma/PBM balance of power may well have shifted—but not to the degree many observers had predicted. Larry Dobrow assesses the aftershocks

During the last few months, nary a week has passed without some kind of new, hysterical dispatch from the front lines of the Gilead/AbbVie/pharmacy benefit manager (PBM)/insurance company hepatitis C battle royal. It all started, as even casual perusers of business news now know, back in December, when Express Scripts struck an exclusive deal with AbbVie that excluded Gilead Sciences' Sovaldi and Harvoni hep.-C drugs from its formulary. In doing so, Express convinced AbbVie to significantly discount the cost of its Viekira Pak therapy, to a point well below the $84,000 sticker price of a Sovaldi regimen.

Reaction came fast and furious. Much of the news media attached a degree of outrage to its analysis of the pricing aspect of the story—$84,000 for a single drug? unconscionable!—that it usually withholds for hot-take commentaries on rogue regimes or Alex Rodriguez. A columnist for TheStreet.com went so far as to characterize the Express Scripts/AbbVie deal as "a serious, perhaps permanent blow to the multiyear biotech stock bull market… The power to control drug prices in the US now has shifted firmly to cost-cutting insurance characters and pharmacy benefit managers." Meanwhile, other newly emboldened PBMs set about striking favorable deals with Gilead or AbbVie. As it progressed, the episode assumed the feel of a high-stakes game of dominoes: Which organization's resolve would be the next to topple?

So now that the dust has settled somewhat, with Gilead and AbbVie sealing hep.-C deals of some sort with one or the other jumbo-size PBM, it's fair to assume that payer-type entities have forever seized the high ground in their transactional relationships with pharma manufacturers, right? That it's wholly, verifiably accurate to say that he who controls access to the formulary is lord of the healthcare manor?

Not quite. By way of illustration, consider the professional experience of Zitter Health Insights senior director of access strategies Melinda Haren—who, in a previous professional life, worked as a registered nurse. "Back then, I was far more concerned about accidental exposure to HCV [hepatitis-C virus] than I was to HIV. Patients sometimes didn't show any symptoms and nobody screened for it," she recalls. "So when I hear that there are these two HCV products that cure the disease—cure it, not make it a little better or whatever—I don't think, 'Oh, the nerve of these drug companies!' I think, 'This is a revolution.' In that sense, Gilead priced their drugs fairly and ethically."

"Mainly what we see today in this category are exclusion-based formularies that exclude a certain number of drugs because they don't offer any clear clinical advantage over other less costly brand or generic alternatives."
— ALBERT THIGPEN, Catamaran

In other words, there remains a whole lot of gray tingeing the blacks and whites of this ongoing debate. Are the US healthcare and insurance systems set up in such a manner that pharma companies and PBM/payer groups are natural adversaries? Yeah, more or less. But a few months after high-profile hep.-C ado, what we're seeing is largely what we've always seen: negotiations between two entities in which there's an ever-shifting balance of power. Factor in wholesale systematic changes effected by the passage of the Affordable Care Act (like a focus on outcomes, a philosophical shift that all parties to the debate applaud), and it's no surprise that formulary access remains in a state of perma-flux.

"As with most pendulums, it never stops in just the right place," quips Dr. Robert Dubois, chief science officer at the National Pharmaceutical Council.

Nonetheless, there's plenty of reason to believe that the relationship between the parties is less hostile and less adversarial than it was during the pre-ACA years, when there existed less true incentive to unite in the pursuit of a common goal (the aforementioned better outcomes). That holds even as PBMs and payers have the upper hand at the moment, owing to the auto-outrage sparked by a $84,000 price tag and the ease of depicting the organization asking for that sum as amoral profiteers.

"I should show you some of the research I've seen around here. If it weren't for tobacco companies, we would be the most hated industry from a PR perspective," says the head of commercial operations at a mid-size specialty pharma firm who isn't authorized by his employer to talk on the record about formulary access, pricing or, well, most anything else. "When all it takes for you to look like the worst person in the world is for someone to say, 'Hey, grandma is on a fixed income. She can't afford to pay you $300 for her treatment, much less $80,000,' that's not a battle you can win."

At the same time, it doesn't appear that payers and PBMs are overplaying the advantage that comes with being perceived as the slightly less evil of two evil parties engaged in a supposedly contentious clash. Many, in fact, seem eager to extend the proverbial olive branch, to work alongside pharma companies and search together for a more balanced, peaceful coexistence amid the shifting demands of the value- and outcomes-based world. Whether this will ultimately help the business achieve the lower-cost, higher-quality care everyone wants is anyone's guess, but amid all the saber rattling it seems that the parties are inching toward some kind of respectful equilibrium.

"We have good relationships with pharmaceutical companies and right now we are working with them proactively to begin conversations and negotiations earlier in the process than ever before," writes Albert Thigpen, SVP, industry relations and supply chain management for Catamaran, one of the largest PBMs, in response to an e-mailed question about whether the balance of power between pharma companies and PBMs/payers has shifted. "Working together to achieve the appropriate balance of access and cost-effectiveness is in everyone's best interest and that's what we are after."

What do folks on the pharma side of the equation have to say about this? "A couple of years ago, as we were looking at changes in the healthcare environment—some coming from the Affordable Care Act but also some relating to taking fragmentation out of the healthcare system—we thought there might be opportunities to work a little differently with payer organizations than we did in the past," says Jeff Huth, SVP, managed markets at Boehringer Ingelheim, specifically alluding to the evolution of his company's research collaboration with PBM/insurance giant Anthem (née WellPoint) and its HealthCore outcomes-research subsidiary. "There are opportunities to collaborate. There are opportunities to jointly identify gaps in care." All together now: Kumbaya, kumbaya.

NO HUGGING, NO LEARNING

There's no single defining takeaway from the hep.-C fracas, no one near truth that pharma companies can fall back upon during the inevitable next pricing-related flare-up with PBMs (and vice versa). At the same time, with fewer than 60 days' worth of hindsight, observers suggest that its impact will continue to be felt for some time.

The reason for this has less to do with price tags or the psychodynamics of the pharma/payer relationship than it does with, well, math. The $84,000 figure captured the attention of the media and the general public, even as pharma companies have priced any number of drugs in any number of therapeutic categories more aggressively than that. But the sharpest pharma thinkers immediately seized upon the details of the "perfect storm," to quote Dubois, in which parties to the hep.-C conflagration found themselves enveloped.

"If you think about expensive drugs and treatments, and you think about their ability to actually cure people, and you think about large numbers of patients who have a given condition—well, that hadn't happened before at the same time," he explains. "The really expensive therapies we've seen typically treated uncommon conditions. With hep. C and the Gilead products, you've got a really expensive therapy but three million people who need it."

Like Dubois, Haren believes the Sovaldi and Harvoni treatment regimens are actually cost-effective. "Eighty-four thousand dollars is a lot of money, don't get me wrong, but it's not a lot of money given the alternative," she says. "The real issue is the exponential growth in the patient population. Before, the therapy would make [patients] feel like they had the flu for three to six months. The adherence rate was less than 10%, so doctors held the drugs for the sickest patients. They knew most people couldn't tolerate it. But now there's no flu anymore … So you've got the same three or four million patients, but instead of 10% in treatment you're going to have everybody in treatment." That, she believes, has to be what prompted Express Scripts to dig in its heels and will prompt others to do so next time.

You can't blame PBMs and payers for seizing the opportunity. With healthcare costs rising every year, it doesn't behoove them to deflect client concerns by shrugging their shoulders and saying, in effect, "My costs are going up and so too shall yours." Amid their recent fits of pique, pharma companies have occasionally lost sight of the fact that payers are under pressure, too. "There are limited places they can effect change. They can't cut costs from doctors. They can't do it with hospitals," Haren says.

In response to another e-mailed question, this one about the state of the union for formulary access from where Catamaran is

The next hep.-C?

Asked to identify the next battleground in the disarmingly civil war between pharma companies and payers/pharmaceutical benefit managers (PBMs), a few pundits point to the upcoming wave of PCSK-9 inhibitors from Pfizer, Sanofi and Amgen. Expected to significantly lower LDL-cholesterol levels and cardiovascular risk in susceptible populations, they will command a premium price for doing so. But most experts believe that there's greater potential for an ugly public skirmish with new cancer drugs, especially those deemed by payers/PBMs as producing only incrementally better outcomes than existing, and less costly, treatments.

Such conflict isn't exactly exclusive to 2015. Organizations within the broadly defined cancer category have demanded (and received) five-figure sums for drugs that produce something less than a cure for some time now. "In oncology, what's going on with hep.-C and Gilead and AbbVie and the PBMs has been happening for years. There's been lots of similar back-and-forth," says Jacque Fisher, EVP and managing director of Maxcess Managed Markets. Melinda Haren, senior director of access strategies for Zitter Health Insights, agrees, adding, "Several oncology drug launches last year had a higher price tag than what Gilead had [for Sovaldi], but you didn't see the uproar in the papers or on the Internet."

That, many healthcare marketers believe, will change in the wake of the contentious and highly public battle over hep.-C drug pricing. On one hand, PBMs will have to proceed delicately in the cancer space. Asking seriously ill cancer patients to mix-and-match with their treatment regimens because certain drugs aren't given a formulary stamp of approval is considered several levels beyond heartless. "Payers have always been a little cautious due to public backlash. Nobody wants to end up as the bad guy in the next Lifetime movie," Haren shrugs.

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—MELINDA HAREN, Zitter Heath Insights

At the same time, many expensive oncology agents offer patients only an incremental boost: extra months of life but only a marginally improved quality of life as opposed to the full-out cures promised by the Gilead and AbbVie hep.-C drugs. At some point payers and PBMs will start asking what breaks they're willing to cut for products that add such incremental value—PR consequences be damned.

To that end, Bloomberg recently reported that Express Scripts has its eye on the oncology category—specifically PD-1 cancer treatments expected to cost in the neighborhood of $150,000. The Bloomberg story featured this ominous quote from Express Scripts' chief medical officer: "We want to be able to start influencing the market by 2016."

The situation is complicated further by evolving treatment options. Take breast cancer as an example. "There's not just one 'breast cancer' anymore," notes Michele Andrews, EVP, payer strategy at Ogilvy Healthworld Payer Marketing. "We used to think a tumor was a tumor, but now we can better understand the molecular profile of each one … Payers are going to want to know—'If I give this expensive drug to this type of patient, is it going to work?'"

Indeed, formulary decision makers have long tapped large populations. They have, to put it less than elegantly, played the odds. In an increasingly fractured cancer-treatment landscape, PBMs and payers can no longer rely on such an approach. Plus cancer-drug advances have been matched by similar progress on the diagnostic front. At some point PBMs and payers will have to contend with the costs that come with more in-depth testing, not to mention an entirely new treatment calculus for individuals deemed to be worthy, or unworthy, of the advanced therapies.

With all this, not surprisingly, comes a host of marketing and communications challenges. "In terms of their receptiveness to all this information that's out there, patients honestly do not pay attention until they need a specific type of treatment," Andrews says. Interested healthcare entities, then, need to reorient their strategies and tactics to provide greater depth of information over time.

"There's a general public health perspective, and then there's a very different type of communication and marketing that will go from a healthcare team to a patient that may have a particular genetic makeup," she continues. "Payers are going to be communicating directly with patients more and more. Manufacturers are going to start providing more context to key stakeholders. It's an interesting and difficult challenge for an interesting time."

sitting, Thigpen acknowledges the pressures. "Given the specialty and overall drug trends we're seeing, drug-price inflation, the end of the patent cliff and more, payers are under pressure to rein in costs while providing high-quality treatment and partially closed formularies allow them to do that," he writes. "Mainly what we see today in this category are exclusion-based formularies that exclude a certain number of drugs because they don't offer any clear clinical advantage over other less costly brand or generic alternatives."

As for pharma companies, they're left to counter these and other jabs with enhanced education efforts, the type of which might've reframed the hep.-C debate in a way that didn't leave Gilead looking like the greediest guy in the room. "It isn't a seesaw. There's an opportunity for a win–win," insists Jacque Fisher, EVP, managing director of Maxcess Managed Markets. "You see a lot of this in European markets—the pharma people, payers and everyone else all come to the table. 'We need to see that there's true value in a high-priced treatment. Let's negotiate a plan we can all live with.' There's lots of transparency in those situations." When asked if US pharma firms and PBMs are coming around to this way of thinking, Fisher sighs audibly. "There's a shift, I guess. For some, it's still all about the volume-rebate story. Everybody's just navigating through all the complexity that we've created for ourselves."

"What's great so far is that nobody's walking around like he has all the answers. It's been a real collaboration."
—JEFF HUTH,
Boehringer Ingelheim

HOWDY, PARTNERS

It's thus worth shining a light on the small but growing number of insurers and pharma companies that have figured out a way to work together for their mutual benefit—and, of course, for the benefit of their members and patients. Notable among them are the research collaborations Anthem and HealthCore have established with AstraZeneca and, more recently, Boehringer Ingelheim and Eli Lilly. Each of the five-year programs is designed to produce forward-minded research in what the Lilly/Anthem/HealthCore December press release alluringly categorizes as "areas of mutual interest."

To hear HealthCore co-founder and VP of research Dr. Mark Cziraky tell it, the collaborations are equally grounded in practicality and commonality of interest. "We're trying to do research that leads not only to generating good information but also causes some change for the better within the system," he explains. "We're identifying gaps in care, but we're also targeting where new therapies can be utilized. We're taking a longer-term view than what you've historically seen, which is basically everybody answering their own siloed questions."

Discussing the HealthCore/Anthem relationships with the three pharma giants, Cziraky comes across as a hopeful pragmatist. He readily acknowledges the tension between PBMs and pharmaceutical companies while at the same time suggesting that such organizations can find common ground if they don't get caught up in minutiae.

"Every party to this cares about the whole cost of care of managing patients," he says. "Drug costs are obviously a component of that, but it's the impact on outcome that's most important. If you get too myopic, you might make decisions that aren't ideal for anyone." These collaborations, then, are more about shifting the dynamic that exists between payer and life-sciences organizations than they are about bridging some perceived philosophical divide.

"Research platforms are the perfect place to begin," Cziraky continues. "They're transparent and, if they're well thought out and designed, everybody is going to be on the same page. We all want what we learn to be utilized in decision making."

As a party to one of the Anthem/HealthCore collaborations, Boehringer's Huth agrees with Cziraky's characterization of the evolving relationship between his company and its budding research partner (the arrangement was announced in November). Prior to making it official, Boehringer conducted what Huth describes as "a landscape assessment," in which the company sussed out the traits it hoped to find in a collaborator.

"Anthem, or WellPoint at that time, appealed to us because they're an insurance company as opposed to a pure-play PBM. We thought they'd be more interested in how pharmaceuticals can fit in the overall scheme of healthcare, rather than [being viewed] as strictly a cost element," he recalls. Also appealing to Huth and his Boehringer colleagues: access to the Anthem/HealthCore cache of data and health records, which they believed would contribute greatly to the recognition of gaps in care.

"We're active in a wide range of therapeutic areas—COPD, diabetes—that are chronic disease areas, and partnerships like this can help us better understand the patient journey," Huth notes enthusiastically. "What's great so far is that nobody's walking around like he has all the answers. It's been a real collaboration."

WHAT LIES AHEAD

So we've got at least one payer/insurer and pharma company discussing each other in terms more often used to describe a dear aunt than a historical foe. We've got continued marshaling of resources on the PBM side of the ball (EnvisionRx recently agreed to be purchased by Rite Aid for somewhere in the neighborhood of $2 billion). And we've got pharma companies ready to roll out transformative new cholesterol and cancer therapies, nearly all of which will be priced in a manner commensurate with their curative properties (see sidebar, p. 29).

Dubois worries about narrowing formularies, that they will give rise to what he calls a "heterogeneity-of-treatment effect" and serve patients poorly. Haren wonders about evolving public perceptions of disease states, fearing that certain types of patients—say, a parent of three stricken with cancer—will be treated better by the system than ones with conditions thought to be the patient's fault (" 'you don't deserve to get treated,' that kind of thing"). Ultimately, though, most observers refrain from specific predictions and side with the unnamed commercial operations exec at the mid-size specialty pharma firm, who believes that the true fireworks are yet to fly.

"It's a game that's going to go back and forth between payers and companies like us for a while," he says. "We're going to give one [PBM] one price and another [PBM] a different one, and see where that leaves us. The PBMs are going to press us on price right up to the point where [a formulary decision] becomes a PR disaster for them. Nobody will come out of this looking good." In other words: If you're into high-stakes games of chicken, you could be in for a real treat. ■