MMIT RADAR

Market Access Spotlight

Actionable understandings from AIS Health's in-depth coverage

February 2018

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Gene Therapies Present Challenges, as Well As Potential for Novel Contracting Tactics

The FDA recently approved the third gene therapy ever when it OK'd Spark Therapeutics, Inc.'s Luxturna (voretigene neparvovec-rzyl). And while these therapies hold a lot of promise, they also present a challenge for various industry stakeholders — and not simply due to their high prices. Complex administration procedures for these one-time treatments — which all have price tags in the hundreds of thousands of dollars — are creating challenges for payers, hospitals and manufacturers, all of which are trying to provide access to these drugs while grappling with a reimbursement approach that may be increasingly outdated when it comes to these new treatments.

A couple of weeks after Luxturna's Dec. 19 approval, Spark unveiled three new contracting models for the $850,000 therapy: an outcomes-based rebate arrangement in which payment is linked to short-term efficacy of 30 to 90 days and longer-term durability of 30 months, a contracting model by which treatment centers will not need to buy and bill for the product, and a proposal to CMS to pay for the drug in installments over several years.

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Focus on Drug Prices, Pharma M&A Activity, 340B Changes Is Expected in Coming Year

As 2018 gears up, it's anyone's guess as to what's in store for the pharmaceutical industry this year. Will drug prices continue to dominate the discussion? What pharma-focused legislation may be in store? AIS Health spoke with an array of industry experts to get their takes on these topics and more.

What pharma trends do you expect we'll see in 2018 with respect to drug development? Legislation? Anything else?

Stephen Cichy, founder and managing director of Monarch Specialty Group, LLC: "Expect continued changes of the 340B program. In November of this past year, [HHS] released a Final Rule implementing a payment reduction for most covered outpatient drugs billed to Medicare by 340B-participating hospitals from the current ASP [i.e., average sales

price] plus 6% rate to ASP minus 22.5%. This represents a payment cut of almost 30%. The payment reduction was made effective Jan. 1, 2018, for all 340B-participating hospitals paid under the Medicare OPPS [i.e., Outpatient Prospective Payment System] with a few exceptions.

"Separately, new legislation was introduced in December 2017 under the name 340B Protecting Access for the Underserved and Safety-net Entities Act (340B PAUSE Act) that proposes to implement a two-year moratorium on most new 340B hospital participants, including both hospitals new to 340B and new locations of existing hospital participants.

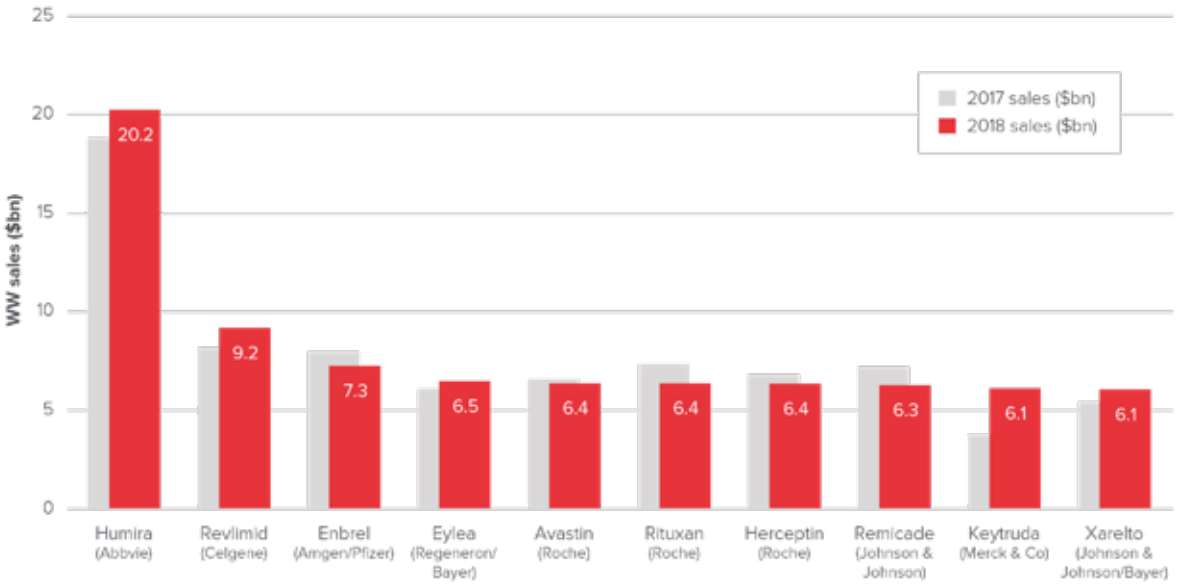
"In addition, expect biosimilars to continue to play-out in the market as a major headline topic. The regulatory policy and legal issues facing biosimilars commercialization will continue to evolve….Policies such as fail-first mandates will gain increasing attention, especially regarding their effects on biosimilars gaining market access.

"A lesser-recognized accomplishment in this past year is the enactment of the enhanced Nurse Licensure Compact [i.e., eNLC], which may play out in a meaningful way for the specialty pharmacy industry in 2018. This compact allows for registered nurses and licensed practical/vocational nurses (LPN/VNs) with a single-state license to practice in person or via telehealth in both their home state and other of 26 participating eNLC states."

Meghan Oates-Zalesky, vice president of marketing for InCrowd: "For tech and research, we'll see consolidation and partnerships, bringing manufacturers the best of both the consulting and innovations worlds.

"There will also be a growing comfort with innovation and technology within the pharma development process. Efforts by market disruptors to demonstrate clear efficacy and value will pay off as they debunk unfounded perceptions of risk. This work will be aided by the compelling call to action to chief executives and operators to create a culture open to innovation and tech enablement within manufacturers all aimed at bringing drugs to market faster.

Top 10 Drugs by 2018 Sales ($bn)



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SOURCE: Evaluate Ltd., *EP Vantage 2018 Preview,* released December 2017. Data from EvaluatePharma, Nov. 15, 2017. Download the report at www.evaluategroup.com/PharmaBiotech2018Preview.

"In regards to legislation, the continued Trump administration trend toward deregulation should work in the pharma industry's favor. However, the repeal of the individual mandate could have repercussions across all of health care, including pharma, as premiums rise at the end of next year. This assumes nothing will be done legislatively to shore-up the individual market and stabilize it, which is likely, as Republicans have worked tirelessly for months to repeal, defund (defenestrate, decapitate, depreciate de-anything they can!) and now collapse the individual market."

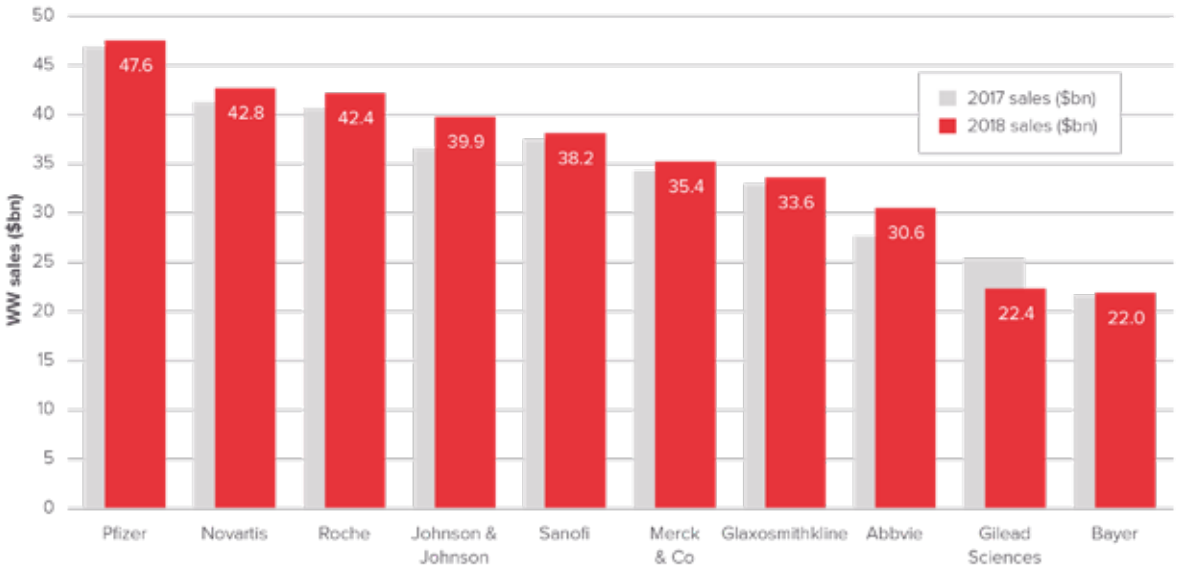
Pharma industry veteran who asked to remain unidentified: "Drug development will see companies backing away from Parkinson's drug development as a result of another high-profile failure and a major advancement using CRISPR to adjust/address individual genes while in the body. There will be no legislation or any serious discussion of anything drug related in 2018."

Jeremy Schafer, senior vice president of payer access solutions at Precision for Value: "I think oncology will continue to grow and expand rapidly as new technologies surface and an aging population creates more market demand. Manufacturers will also face continued pressure on proving value and justifying both base price and price increases. In terms of legislation, I think we will see quite a bit of promises or threats of drug price legislation, especially as the campaigning for November 2018 heats up, but I am less certain we will see actual drug price legislation in 2018. We may also see some court outcomes in areas significant to pharma like the 340B cutback from CMS and the challenge to California's SB17."

Are there any therapies in the pipeline that you're watching closely?

Cichy: "In August of this past year Gilead announced FDA priority review for its planned integrase inhibitor bictegravir/F/TAF, which [it] anticipates to compete with Glaxo's dolutegravir — marketed as Tivicay — if it wins approval in 2018. Despite the large number of drugs currently approved

The Biggest Pharma Companies – Rx and OTC Sales



WW = worldwide

SOURCE: Evaluate Ltd., *EP Vantage 2018 Preview,* released December 2017. Data from EvaluatePharma, Nov. 15, 2017. Download the report at www.evaluategroup.com/PharmaBiotech2018Preview.

for HIV, distinct unmet needs continue to exist for an FDA-approved medication with a strong safety profile that offers simple regimens and dosing frequency.

"Incyte's epacadostat is an anticipated cancer immunotherapy to watch for this year. Incyte's clinical data appears to be stacking up well against the combination of Bristol-Myers' Opdivo and Yervoy, which won FDA approval in early 2017 for the treatment of patients with advanced melanoma.

"In November of this past year, the FDA approved Genentech's Hemlibra for hemophilia A with inhibitors. This is the only indicated medicine that can be self-administered once weekly by injection subcutaneously. It's [anticipated that] Genentech's discount pricing strategy with Hemlibra versus the current standard of care will aid adoption and penetration of the market in 2018.

"Pricing will continue to be a front-page topic."

"Celgene's ozanimod is another potential new drug to watch for in 2018. Ozanimod is one of the late-stage candidates in Celgene's inflammation and immunology pipeline and a potential blockbuster drug in the increasingly crowded multiple sclerosis space.

"Also look for AbbVie's endometriosis drug elagolix to make some headlines in 2018. The FDA recently granted priority review for this drug, and an approval decision is expected in the early part of 2018.

"We also like Sage's brexanalone. Sage is currently conducting Phase III studies evaluating the impact of brexanalone in the treatment of adult female subjects with moderate to severe postpartum depression. What make this drug notable, among other things, is its 30-hour continuous infusion requirement. This will require participation of the home infusion pharmacy for medication and nursing support, and may serve as an industry enabler."

Oates-Zalesky: "I watch the immune-oncology market closely. It's volatile, which offers potential promise for those in the space. It will continue to grow in 2018 — there are dozens of therapies in the pipeline now from the top pharma companies — addressing new indications, fewer side effects and other variations. It'll remain highly competitive."

Schafer: "I am watching some of the emerging gene therapies, especially in hemophilia. It will be interesting to see if these drugs continue to see success in clinical trials, whether the responses are durable and if new safety issues arise when tested in larger populations. I am also watching the pipeline in Alzheimer's including both the anti-amyloid therapies and the BACE [i.e., beta secretase cleaving enzyme] agents to see if manufacturers can finally have some success in modifying the course of this devastating disease."

There has been a lot of attention on the prices of drugs, particularly specialty drugs. What do you expect to see on the issue of pricing in 2018? Are there particular drugs/classes of drugs that you expect to see a focus on?

Martin Burruano, vice president for pharmacy at Independent Health, and Amy Nash, president of Reliance Rx, the specialty pharmacy subsidiary of Independent Health: "Although there will be less frequent price increases, specialty drug prices will still increase. As lower price alternatives are approved for some products (i.e., biosimilars), there will be more pressure on the brand manufacturers to be competitive. Focus will be on utilization management and preferred drugs where there may be more cost-effective alternatives for the continued high drug costs and newly approved drugs for rare diseases and oncology, as the majority of the drug cost trend is in the management of medical drug spend on the medical vs. pharmacy benefit."

Cichy: "Pricing will continue to be a front-page topic, although I'm not certain that we're going to hear the same high volume on this topic that we experienced in 2017. Based on our recent experience with our clients, it doesn't feel like the level of price trend is accelerating as [it] was in years past. Instead, we expect for specialty generics to gain increasing attention as a potentially feasible counterbalance to specialty spend. We've already had Copaxone 40mg

and Gleevec come to market, and Tracleer is coming down the pipe shortly.

"We're also expecting to see a continuing shift away from open specialty networks, especially for drugs within certain therapeutic categories where managing the patient with disease specific programs is viewed to be important by the payer.

"Look for hepatitis C, rheumatoid arthritis, multiple sclerosis and oncology to dominate payer focus. Additional areas of interest will include those areas characterized by high-cost drugs with a more-than-usual expense trend."

"Look for increased industry consolidation."

April Kunze, Pharm.D., senior director, clinical formulary development and trend management strategy, Prime Therapeutics, LLC: "We will continue to see multiple drug submissions for orphan conditions and oncology indications, both for new drug entities and supplemental new drug applications, which expand the use of a drug. Orphan drugs are often launching at more than $500,000 annually, and many of the new oncology drugs are launching at $180,000 or more per year. Although these are not used by a broad population, any use can significantly impact drug trend. Additionally, many of these drugs show marginal clinical improvement."

Jeff Myers, president and CEO of Medicaid Health Plans of America: Last year, the pharma industry managed to avoid "even the slightest discussion of any change to policy that might lower prices to consumers and to taxpayers, who pay for a vast amount of pharmaceuticals." Manufacturers faced "the threat of some discussion about the ridiculousness of drug prices, which they successfully squelched." Among impacts so far from the Republican-led White House, administration and Congress, "FDA Commissioner Scott Gottlieb's willingness to speak some truth to power about the costs of drugs and things that FDA can do to accelerate generic approvals and others" stands out.

Oates-Zalesky: "In regard to pricing it's hard to imagine it won't increase in 2018, just given the instability of the current administration, the lack of consideration applied to the repeal of the individual mandate and the ripple effect that could have, and even in spite of Trump's efforts to deregulate."

Schafer: "I think pricing will continue to be controversial leading into 2018 and will probably gain more steam as the elections approach since drug pricing is an area of concern for many Americans that both parties can leverage to entice voters. Oncology, given the life-or-death nature of the disease, is a popular target for drug price discussions, and we will probably see more of that in 2018, especially as more combination regimens are approved.

"On the manufacturer side, we did see some manufacturers in the specialty space launch products at prices lower than expected, which is a change from the norm of price parity. I would expect to see more of this in the future as well, especially if these manufacturers are rewarded with strong access from payers and are able to achieve their sales goals."

Mesfin Tegenu, president of PerformRx: "In 2017, at least in our experience, we were lucky enough to see lower-than-expected specialty trend numbers as the result of cost reductions for hepatitis C therapies. However, we anticipate that the 2018 specialty trend will return to the 18%-25% levels we've seen in past years. We are starting to see more specialty products coming to market that are used for conditions that have a significant patient population involved."

How do you think a Republican-led White House, administration and Congress will impact the pharma industry next year?

Myers: "It will continue to let the industry do what it does, without fear of change or reputational impact."

Oates-Zalesky: "I believe the administration's intention will be to deregulate and let market forces drive costs. I suspect there'll be an effort made to facilitate — and speed up — the drug approval process and approve more drugs for market in the coming

year. But like so many things for which the Trump administration has aspired, the reality is much more complicated than he and others had suspected. As such, this aspiration will not be met."

Schafer: "I think the Republican-led government will likely continue the approach favoring free markets as they generally do. I would expect to see lightened regulations which may allow faster drug approvals but also the release of more generics and biosimilars, which will increase competition. The government may also act on areas that are generally unpopular like pay to delay and other arrangements that weaken the ability of lower cost alternatives to come to market."

What kind of merger and acquisition (M&A) activity within the pharma industry might we see in 2018?

Cichy: "The overall M&A marketplace was slightly bearish in 2017. A meaningful part of this may have been deal fatigue among the more prolific acquirers. Company tax positions will be lower in lieu of the recent tax reform, which may provide increased flexibility for deal making as we move into 2018. Look for increased industry consolidation with this change, as both manufacturers and pharmacies seek to leverage size/scale as a counterbalance against industry pricing pressure."

Oates-Zalesky: "Rather than traditional M&A, in 2018, I believe there will be more of a focus on tech acquisitions that enable faster time to market, accelerating various functions of the drug development process (e.g., discovery, patient recruiting, endpoint design, communication, among others)."

Pharma industry veteran who asked to remain unidentified: "Lots — with all of the additional repatriated dollars, expect at least one megamerger (maybe Bristol-Myers Squibb?) and several biotechs to get rolled up."

Schafer: "I think we will continue to see manufacturers eyeing opportunities for the 'next big thing' by looking for small manufacturers with promising technologies, particularly in oncology, to acquire these molecules. We could also see some larger M&A if manufacturers bring in their off-shore reserves and decide to make some big buys, especially with the election uncertainty now behind them."

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by Angela Maas

PAPs Benefit Patients but Can Have Legal and Business Risks

Drug pricing and distribution practices are confusing and complicated for everyone, but especially so for patients seeking financial assistance with drug costs. "The guiding principle in all this should be to keep the best interests of the patient at heart," says Valerie Sullivan, an industry consultant and former president of inVentiv Patient Access Solutions, a service provider to pharma companies running their patient support programs.

As the health exchanges established by the Affordable Care Act (ACA) went into effect in 2014, the number of uninsured was estimated at 47 million and the number of underinsured at 41 million. The ACA brought both numbers down to some degree, but underinsurance — defined as spending either 5% or 10% or more of family income, depending on relative level of wealth, on health care — could also increase if patients with high-deductible plans need more expensive medications. (There are also underinsured consumers who have employer-based health plans.) With the changes to the ACA in the past year, it's likely that uninsured and underinsured numbers will start going up again.

The term "patient assistance" can refer to any type of unreimbursed or free support of patients, including the provision of health services at, for example, a free clinic. Patient assistance programs (PAPs) usually refer to the mechanisms to support patients who need

drugs they can't afford. There are a bewildering variety of PAPs, coming from many directions and with many options:

- ◇ ***Free drugs from pharma manufacturers;***
- ◇ ***Charities that support health care;***
- ◇ ***Foundations or patient-advocacy groups that reimburse patients;***
- ◇ ***Copay coupons and vouchers, generally funded by pharma manufacturers, to supplement insurance deductibles;*** and
- ◇ ***Pharmacy benefit cards (aka discount drug cards) offering varying degrees of discounting (usually for generics).***

There are also some behind-the-scenes programs that ostensibly help patients who need drugs, in particular the 340B program that enables qualified hospitals serving the needy to acquire drugs at discounts of around 50%.

To be even more specific, PAPs usually are mentioned in the context of programs that are directly or indirectly supported by the pharma industry itself. There is a bright, sunny side to these PAPs, and there is a dark side. Let's look at both.

The Bright Side

In the mid-2000s, when a round of drug price increases heightened public concern over medication costs, the industry's trade association, the Pharmaceutical Research and Manufacturers Association, centralized information about PAPs as the Partnership for Prescription Assistance (PPA). Since 2005, according to PhRMA, PPA has assisted more than 10 million patients, has 60 medical and charitable organizations as partners, and lists 15 discount drug card programs (not endorsing any of them) and 74 programs run by PhRMA members, which are among the largest pharma companies in the country.

Firms pump billions of dollars into their PAPs. Generally speaking, pharma companies have considerable latitude from regulators in giving away their products under free drug programs. Usually these have restrictions based on the level of income of the recipient, and they also have a term limit — typically one year — although patients can re-apply.

In cases where a pharma company cannot provide copay assistance directly to a patient, an alternative is to provide funding to a foundation. There is a cutoff here; the pharma company cannot guide the foundation's actions, and the foundation cannot share patient information with manufacturers or other donors. The Healthwell Foundation, as one example, distributed $168 million in copay assistance (and other types of support) in 2016, provided through dozens of "disease funds" that are not tied to a particular drug. The downside for a pharma manufacturer contributing to a foundation like this is that its contribution might in fact support a competitor's drug.

"The guiding principle in all this should be to keep the best interests of the patient at heart."

A similar foundation, Patient Services, Inc. (PSI), seems to be walking right up to the line where regulators would look askance at the foundation's support of commercial activity. The foundation's website includes a page saying that PSI "is an expert in helping pharmaceutical companies emerging from clinical trials to introduce their new approved drug to the commercial population in the specific area of patient assistance" and that "PSI has helped new pharmaceutical companies develop needed comprehensive patient assistance programs for rare disorder specialized drug distribution." PSI sued CMS in January, citing free-speech rights, after CMS instituted a policy forbidding asking "donors and potential donors for information that only corporate donors would possess about a wide range of issues, including diseases, drugs and patient populations," according to PSI. This information, says PSI, "is critical for PSI to know in order to create programs to help patients." (It's worth noting that CMS is not litigating against PSI at this time and that PSI has been in routine communication with CMS since its founding in 2003.)

A final common source of PAP support is drug discount cards. Generally speaking, these do not have

pharma manufacturer support, but rather come about from competition among PBMs and among pharmacy networks. The discounts they provide — which can be real — originate in the discounted prices that PBMs get for drugs they have on their formularies or from one pharmacy chain competing against another for market share and consumer traffic. Drug discount cards are almost always not available for use with insurance, so from the pharmacy and PBM perspective, they are a low-cost way to expand their consumer base, while doing good for cash-paying patients.

The Dark Side

When health advocates and social commentators are not complaining about the high prices charged for drugs, they are complaining about an assumed hypocrisy in how manufacturers pump up their market share through PAPs. After a free-drug program runs out, they say, patients are compelled to somehow afford the drug. Copay cards likewise "hook" patients onto an expensive drug when cheaper alternatives might be available, and the rationale for helping patients stay adherent to the therapy through initial PAP support ultimately means more drug sales for the manufacturer.

Patient support by drugmakers probably has existed as long as the drugmakers themselves, but in the modern era of highly regulated business and commercial practices, PAPs can be a complicated dance among the industry, the businesses that are intermediaries between manufacturers and patients, and regulators. The biggest gatekeeper is the federal government which, under the anti-kickback statutes and the False Claims Act, restricts financial incentives to patients whose health care costs are covered by Medicare and Medicaid.

A 2014 report from the HHS Office of Inspector General (OIG) found that while "manufacturers provide notices directed to beneficiaries and pharmacists that coupons may not be used in Federal health care programs," the method by which Medicare reimbursements are processed leaves gaps, causing improper accounting of the coupons.

PBMs, in particular, have had a running battle with manufacturers over copay programs, which can undercut the formulary tiers so carefully constructed by PBMs. "Drug coupons and copay assistance programs undermine employers' ability to use utilization management tools, such as varying copay amounts for different-priced drugs, to reduce drug costs. Since the use of copay coupons reduces the utilization of more affordable medication options, overall prescription drug costs will continue to increase dramatically," says the Pharmaceutical Care Management Association (PCMA), the lead trade association for big PBMs.

"The latest trend in this area is so-called 'copay accumulator' programs, under which a payer puts a limit on how much copay assistance a patient receives, and above that limit the copay does not go against the deductible of the insurance plan," says Dave MacLeod, senior director, patient services and channel operations at Intercept Pharmaceuticals. For example, he says, a plan might have a $1,000 accumulator limit, and above that, essentially every dollar of copay assistance the patient receives is added to the deductible level.

"You can't shoot from the hip."

PBMs pride themselves on hard-nosed negotiating for rebates for the drugs on their formularies — but those rebates have caught the public's attention because the rebated price is not passed directly over to the payer, and in cases where patients need to pay a portion of the drug's actual cost, the payment can be based on the drug's non-discounted cost, with the PBM pocketing the difference.

Almost by default, the cop to police these commercial battles is federal regulators, and over recent years nearly every type of company in the health care business has been sued or penalized by CMS. In December, United Therapeutics paid a $210 million fine over alleged violations in its relationship with a charity, Caring Voice Foundation, over how Medicare patients were directed to the charity for copayment support (thus enabling patients to get the drug while United Therapeutics benefited from the Medicare reimbursement); similar investigations are going on among other pharma companies.

On the flip side, insurers have been penalized by CMS for violating CMS regulations by improperly denying access to drugs for Medicare patients, impeding access through mismanaging the prior-authorization process, or requiring improper out-of-pocket payments. A CMS website lists 138 organizations that have been hit with penalties or suspended from accepting Medicare patients over such issues.

Even the drug discount cards have run afoul of federal regulations. Walgreens Boots Alliance, Inc. paid a $50 million fine for violating the anti-kickback statute last January, after admitting to enrolling hundreds of thousands of consumers in its Prescription Savings Club program without checking their Medicare and Medicaid status.

Construct PAPs Carefully

Meanwhile, PCMA has been lobbying against a variety of legislative or regulatory proposals in Congress or at CMS involving mandating rebated prices at the point of sale to patients and so-called "any willing pharmacy" provisions to enable pharmacies to obtain better reimbursement from PBMs. (A variety of state legislatures have also taken up these issues.)

Pharma companies are deeply engaged in the patient-assistance processes, even with the risks inherent in them. "PAPs need to be constructed carefully; you can't shoot from the hip," notes industry consultant Sullivan. "Besides the product management team, legal, medical affairs and business management need to be engaged." And when outside hub or patient-support service providers are engaged to manage the programs, "you want to be dealing with a strong service provider, including one that has the chutzpah to tell you when you might be crossing a line."

Intercept Pharma's MacLeod, who has engaged an outside service provider to manage the company's PAP programs, advocates for a close relationship between the manufacturer and the service provider. "We consider our contractor to be a part of our team; their care coordinators are the front line in interacting with patients and health care providers, and we have an ongoing dialogue in which our service provider can have an impact on our business practices," he says. Ultimately, though, any actions of such service providers are the responsibility of the pharma company itself from a regulator's perspective, so trust is essential.

View the OIG report at https://tinyurl.com/yaame8lz. View the CMS enforcement actions website at https://tinyurl.com/zxro46x. ✧

This article was contributed by Nick Basta of Pharmaceutical Commerce. *For more information, visit http://pharmaceuticalcommerce.com.*

Sandoz Executive Talks Zarxio Rollout, Biosimilar Education

When Zarxio (filgrastim-sndz) launched in September 2015, it was the first drug on the U.S. market approved through the 351(k) pathway, which was established by the Biologics Price Competition and Innovation Act of 2009 (BPCIA) as part of the Affordable Care Act. The agency granted Sandoz Inc.'s white blood cell modifier approval for all five indications of its reference drug, Amgen Inc.'s Neupogen (filgrastim), a move underscoring the FDA's confidence in the biosimilar's safety, purity and potency.

In bringing Zarxio to the U.S. market, Sandoz, a Novartis division, also posed one of the first challenges to the BPCIA, maintaining that the so-called "patent dance" and 180 days' marketing notice following approval were optional. Amgen sued the company for patent infringement, and the case has wound its way through several courts, including the Supreme Court last summer. The case seems to have finally been resolved in December, when the Federal Circuit Court of Appeals sided with Sandoz (see story, p. 13).

And although Zarxio's approval came almost five years to the day that the 351(k) biosimilar pathway was established, the FDA has approved eight more biosimilars since that initial approval less than three years ago. AIS Health spoke with Sheila Frame, vice president and head of biopharmaceuticals, North America, at Sandoz, about the company's biosimilars experience in the U.S. and the overall biosimilars market here.

AIS Health: In September 2015, Zarxio became the first biosimilar to launch in the United States. What have you learned about the U.S. market vs. the European experience since then?

Frame: Biosimilar medicines have been used for more than a decade in the EU. Data continues to reinforce that biosimilars show the same safety and efficacy as the reference medicine, without differences in immunogenicity. We know our customers will become increasingly confident with biosimilars as more are on the market and patient numbers and impact grow. This reinforces our real-world experience where Zarxio is at approximately 36% market share and has surpassed the originator product in volume market share in the pre-filled syringe segment.

In general, we expect adoption to vary based on the market, type of payer, channel, nature of therapy and site of care — such as self-administration compared to physician offices or hospital. There may be differences for mAbs [i.e., monoclonal antibodies] in oncology or immunology where treatment is of longer duration, or for chronic use vs. products in supportive care.

Study Shows Oncologists' Confidence

A recent Decision Resources Group study reinforced that U.S. oncologists are interested in prescribing biosimilars (96%) and have confidence in extrapolation (approximately 90%).

AIS Health: How would you compare the rollout of Zarxio vs. a brand drug vs. a generic drug?

Frame: Biosimilars have already had a positive impact on the health care system. With Zarxio, which was the first biosimilar approved through the BPCIA pathway, more than 85,000 patients have already been treated. This biosimilar medicine is the market leader in pre-filled syringes.

We are beginning to see healthy, competitive pricing markets as a result of lower list and average selling prices for products where biosimilars are approved in the U.S., but this is a nascent market. It is important to keep educating physicians, payers and other key stakeholders about the important role that biosimilars play in the future of health care.

AIS Health: Have there been any challenges you've experienced in the U.S. with Zarxio, and, if so, how did you deal with those?

Frame: Biosimilars are not generics, and they are not traditional reference biologics. Therefore, we are still building the blueprint for how biosimilars are commercialized. With over 85,000 patients treated on the first biosimilar brought to market through the BPCIA pathway, Zarxio, we have learned a lot and continue to refine our strategy.

AIS Health: What kind of physician education have you undertaken?

Frame: One key focus area is education and increased awareness, primarily directed at patients and HCPs [i.e., health care professionals], that leads to acceptance of biosimilars. Education requires a multistakeholder approach. Balanced, accurate biosimilars education is the responsibility of industry, managed care, professional societies, trade associations, patient advocacy groups and government.

AIS Health: What kind of payer outreach have you undergone?

Frame: Today, Novartis/Sandoz provides vast clinical and health economic data to help payers compare the value (cost per outcome) of our products to alternative treatments and make the best purchasing and reimbursement decisions. We believe that by collaborating with payers on solutions for reimbursement, we can help start a shift toward value pricing in the health care system moving from a transactional relationship with payers, to one that incentivizes patient outcomes.

Payers, in addition to other key stakeholders including policymakers, health care providers and patients, play a role in supporting a competitive biosimilars marketplace. Biosimilars, which are FDA-approved based on evidence that they match the safety, efficacy and quality profile of their biologic reference products, are already saving the health system money and could reduce direct spending on biologics by more than $54 billion in the U.S. in the next decade ($250 billion globally by 2026). Payers are likely to

see a substantial part of those savings, which could potentially be used to expand access to life-enhancing or innovative medicines. It's important for payers to make the investment in biosimilars now to reap the benefits of biosimilars currently on the market and continue to foster competition, which will ultimately result in greater cost savings in the long-term.

AIS Health: Are there any particular misunderstandings around biosimilars that you'd like to correct?

Frame: It is important that we stay focused on increasing patient access to biosimilar medication while introducing competition into the marketplace. This means ensuring biosimilar value is delivered through a healthy, competitive marketplace. We are beginning to see healthy, competitive pricing markets as a result of lower list and average selling prices, but this is a nascent market. Therefore, we must keep educating physicians, patients and patient groups, payers and other key stakeholders about the important role that biosimilars play in the future of health care.

Additionally, as biosimilar usage increases, we are seeing more aggressive campaigns created to slow uptake. One example is related to switching from a reference product to a biosimilar. Sandoz acknowledges why stable patients would have a concern if they are switched from something that works to a completely different molecule. However, biosimilars have an identical amino acid sequence and an indistinguishable three-dimensional shape. For other biologic or structural characteristics where there may be differences between the reference product and corresponding biosimilar, it must be demonstrated that there is no impact to efficacy, safety or immunogenicity. Sandoz has more than 10 years of biosimilar experience and 340 million patient days of experience across 86 countries. Real-world experience affirms the FDA's statement that patients and health care professionals can expect the same safety and efficacy from an FDA-approved biosimilar as they do from the reference product.

Similarly, with the release of the draft FDA guidance on interchangeability, it is important for the agency to be clear that an interchangeable designation is a request for additional, specific data, beyond the rigorous and high bar set for FDA biologic and biosimilar approval. The FDA does not have more than one standard of product quality for the approval of biologics or biosimilars. Also, the safety and efficacy profiles of biosimilars and their reference medicine are the same regardless of an interchangeability designation.

AIS Health: What is the potential for biosimilars in the U.S.?

Frame: Biologic medicines, produced from living organisms, have revolutionized treatment and prevention of many disabling and life-threatening diseases in recent decades. However, their complexity, combined with a historic lack of competition, means that patient access remains a key challenge, even in highly developed markets.

Biosimilars, which are new versions of existing biologics that match their reference product in terms of quality, safety and efficacy, are key to increasing access to these life-saving medicines and can play a transformational role in health care by generating cost savings directly and indirectly and improving patient access to medication.

In fact, a recent study conducted by RAND Corp. estimated that a competitive biosimilars marketplace could potentially save $54 billion over the next decade. Payers, providers, patients and taxpayers would all realize these savings.

Additionally, a new analysis published by Avalere Health for the Biosimilars Council suggests that 1.2 million U.S. patients could gain access to biologics by 2025 as the result of biosimilar availability. These data also suggest that women, lower income and elderly patients would particularly benefit from access to biosimilar medicines.

AIS Health: The FDA has put out multiple draft and final guidances on biosimilars. Perhaps the most high-profile one is on naming, with the agency calling for four-letter suffixes for not only biosimilars but all biologics. Can you comment on this approach and why it is/is not necessary?

Frame: Sandoz appreciates that the FDA has been working to clarify issues pertaining to nonproprietary

naming of biologic drugs, and has submitted commentary to the Office of Management and Budget (OMB) to consider as they decide on potential implementation of the final guidance.

We maintain our position that there is no need to assign non-meaningful, unique suffixes to the nonproprietary names of all currently-licensed biologics or those to be licensed in the future. While the FDA contends in its guidance that unique suffixes are necessary to ensure patient safety, we believe that they will not provide additional value beyond that of the current naming system, which has been used successfully for over six decades, and that non-meaningful suffixes may actually cause confusion among providers that could lead to risks for patients. In the U.S., as well as worldwide, biologics have been used for many years with shared nonproprietary names, their very purpose being to advise physicians of the active ingredients in all drugs as well as biologics. There is no basis to believe that shared nonproprietary names have created a safety issue for patients.

"Education requires a multistakeholder approach."

Additionally, we believe the cost burden of potential implementation of the naming convention is significantly underestimated in the FDA's guidance. Based on our expertise in the licensing of biologics and biosimilars, we believe the implementation of these naming rules could present an annual cost burden for new 351(a) and 351(k) BLAs [i.e., biologics license applications] applicants conservatively estimated at $4,510,800. The cost of one-time efforts for organizations in the health care system other than the applicant to implement this naming convention can be conservatively estimated at $524,504,000. However, we believe these are likely very low estimates, and the cost to the U.S. health care system could exceed $1 billion. As a worldwide leader with more than 35 years of experience in manufacturing biologics and approved biosimilar products in more than 75 countries, we hope that the OMB will consider the significant financial burden on our health care system and associated risks to patients.

AIS Health: What is the status of your Neulasta (pegfilgrastim) biosimilar?

Frame: We are expecting to refile in the U.S. in 2019.

AIS Health: How many other biosimilars do you have in development? When do you expect to submit those for approval?

Frame: Sandoz is committed to increasing patient access to high-quality biosimilars. We are the global leader in biosimilars, with five biosimilars currently marketed in various countries, as well as a leading global pipeline. Sandoz biosimilar rituximab, marketed as Rixathon, was approved by the European Commission (EC) in June 2017 and is currently under review by the FDA. Sandoz biosimilar adalimumab is currently being reviewed by the European Medicines Agency (EMA). Sandoz also plans to launch five biosimilars of major oncology and immunology biologics across key geographies by 2020.

AIS Health: Pfizer recently brought a lawsuit against Johnson & Johnson over contracting for Remicade (infliximab), saying it is using anticompetitive practices to effectively prevent uptake of Inflectra (infliximab-dyyb). Do you have any comments on that?

Frame: It's critical that biosimilar value is delivered through a healthy, competitive marketplace. In order for patients to experience greater access and health care systems to see greater savings through direct and indirect cost savings, biosimilars must be covered, prescribed and used if we are to realize their full promise. The conversation that is unfolding related to exclusionary contracts is an important one, and we look forward to seeing how this develops.

Contact Frame through Randi Kahn at kahnr@ruderfinn.com. ✧

by Angela Maas

This story was reprinted from AIS Health's monthly publication Radar on Specialty Pharmacy. *For more information, visit https://marketplace.aishealth.com/product/specialty-pharmacy.*

In Ongoing Battle, Court Says BPCIA Pre-empts State Law

As part of the process of bringing the first biosimilar, Zarxio (filgrastim-sndz), onto the U.S. market, Sandoz Inc. decided to challenge portions of the Biologics Price Competition and Innovation Act of 2009 (BPCIA). When Congress passed the BPCIA as part of the Affordable Care Act, it left many of the details up to the FDA. Two of those issues were whether the "patent dance" is mandatory and what the timeline is for when a biosimilar manufacturer needs to notify the reference drug sponsor of its intent to market the drug. The company's move prompted a lawsuit from Amgen Inc., manufacturer of Zarxio reference drug Neupogen (filgrastim), in a case that appears to finally have been resolved recently, when, on Dec. 14, the U.S. Court of Appeals for the Federal Circuit sided with Sandoz.

The situation began one day after the FDA notified Sandoz on July 7, 2014, that it had accepted for review the company's abbreviated biologics license application for Zarxio, when Sandoz notified Amgen that it had submitted that application and would market the drug upon approval rather than waiting 180 days from that date. Sandoz also said later that it would not give Amgen its application and manufacturing information because the patent dance, a series of steps for the exchange of information between the biosimilar applicant and the reference drug sponsor, was not mandatory.

"Amgen's state law claims conflict with the BPCIA."

A few months later on Oct. 24, Amgen sued Sandoz for patent infringement, citing California's unfair competition law as well as the BPCIA. It asked the U.S. District Court for the Northern District of California to issue injunctions to force Sandoz to follow the patent dance and to wait until the FDA licensed Zarxio to give Amgen 180 days' notice.

The lawsuit (No. 15-1499) wound its way through various courts before finally landing at the Supreme Court, which ruled June 12, 2017, that the patent dance was not mandatory and that biosimilar applicants need not wait for FDA approval to notify reference drug manufacturers of their intent to market the drugs. The court, however, did not respond to whether a company could get an injunction under a state law, and it remanded this part of the case to the Federal Circuit.

That court ruled in December that state law claims are pre-empted by the BPCIA. "Because Sandoz did not forfeit its preemption defense and the BPCIA preempts state law remedies for an applicant's failure to comply with § 262(l)(2)(A), we now affirm the district court's dismissal of Amgen's state law claims," said the court. "We affirm the dismissal of Amgen's unfair competition and conversion claims. Amgen's state law claims are preempted on both field and conflict grounds."

According to the court, "the preemption analysis here demonstrates that Amgen's state law claims conflict with the BPCIA and intrude upon a field, biosimilar patent litigation, that Congress reserved for the federal government."

'Important Win for Patient Access'

Sheila Frame, vice president and head of biopharmaceuticals, North America at Sandoz, tells AIS Heath, "The Federal Circuit issued its ruling on the outstanding legal questions from the Supreme Court decision in *Sandoz v Amgen*. In that case, the Supreme Court found that a biosimilar applicant cannot be ordered under federal law to participate in the 'patent dance' or to provide a notice of commercial marketing. The Federal Circuit today found that a biosimilar applicant also cannot be ordered to take those actions under state law.

"This is an important win for patient access to life-changing biosimilar medication," continues Frame. "While reference medicine manufacturers will no doubt try and continue to use the legal system to create unnecessary and costly barriers that delay biosimilar approval or availability, this is one of several wins this year that prove the tide is turning for broad-based biosimilar access. We look forward to working closely with other key stakeholders to advocate on behalf of

patients and deliver on the access and value promise of biosimilar medicines."

View the decision at https://tinyurl.com/yc6taoly. Contact Frame through Randi Kahn at kahnr@ruderfinn.com. ✧

by Angela Maas

This story was reprinted from AIS Health's monthly publication Radar on Specialty Pharmacy. *For more information, visit https://marketplace.aishealth.com/product/specialty-pharmacy.*

Gene Therapies Bring Complexity

continued from p. 1

Spark said it has agreed in principle with Harvard Pilgrim Health Care, Inc. on the outcomes-based rebate arrangement. In addition, the manufacturer is working with Express Scripts Holding Co. to help offer an alternative to buy and bill. Through that arrangement, rather than the provider purchasing the therapy, as is common with therapies adjudicated through the medical benefit, Express Scripts will provide Luxturna through Accredo Specialty Pharmacy and CuraScript Specialty Distribution, explains Steve Miller, M.D., chief medical officer at Express Scripts. For "our PBM clients, like with Harvard Pilgrim, the value-based contract has bookends at 30 to 90 days and at 30 months."

Miller says that Express Scripts learned from its experience with spinal muscular atrophy drug Spinraza (nusinersen). He notes that Express Scripts is the exclusive provider of the therapy, which costs $750,000 for the first year of treatment and $375,000 every year after that. The condition, he points out, is "pretty rare," and the drug is given intrathecally; "it's not a self-administered, easy drug."

"Many health centers did not want to buy Spinraza" because they didn't want to stock it, he tells AIS Health. It has special handling requirements, and if it's stored improperly or a vial is broken, that center is out "hundreds of thousands of dollars," explains Miller. So Express Scripts offers two ways that centers can get the drug. "We will dispense it from Accredo Specialty Pharmacy" in a patient-specific dose that's shipped directly to the procedure room for administration by a neurologist or other health care professional.

"We also sell Spinraza through our distribution company, CuraScript Specialty Distribution," he says. "We want to make it flexible for however" payers and providers want the drug distributed.

"We'll take the risk of holding the product."

The manufacturer of the first gene therapy also took an innovative contracting approach. When the FDA approved Novartis Pharmaceuticals Corp.'s chimeric antigen receptor T cell (CAR-T) therapy Kymriah (tisagenlecleucel) in late August, CEO Joseph Jimenez said the company had reached "a novel collaboration" with CMS for an outcomes-based approach for the $475,000 therapy.

Lack of Specific Codes Causes Issues

But the second approved gene therapy has had a somewhat different experience: According to a Dec. 14 Bloomberg article, two months after the FDA's approval of Kite Pharma, Inc.'s Yescarta (axicabtagene ciloleucel), only five people have been treated with the $373,000 therapy as waiting lists for the treatment "have grown to at least 200 people, shrinking only as some very sick patients have died." According to the article, "Doctors at the cancer centers blame holdups in getting the treatment paid for by Medicare and Medicaid,...as well as some of the U.S.'s largest insurers." Without a reimbursement code for the drug — and, thus, a guarantee of payment — hospitals have been reluctant to shell out for the therapy.

"The inability to gain a 'guarantee of payment' is inherent to the claim processing process of today, especially when a specific code has not been issued," explains Winston Wong, Pharm.D., president of W-Squared Group. "It is well-known that it takes six to nine months for a specific HCPCS code to be issued." This process, he tells AIS Health, "has not changed. What has changed, which brings this topic to a higher level of sensitivity, is the high cost burden these new medications represent. With the higher cost burden comes the higher cost risk that must be borne by the provider stakeholders. In short, this is not a new

situation, only an intensified situation where there is no quick and easy solution."

According to Jeremy Schafer, senior vice president, director – payer access solutions at Precision for Value, "The adoption of gene therapies isn't just complicated by price, but also by the fact that the cost comes all at once. Hospitals are not new to the idea of using drugs without product-specific codes — they do it all the time. If a hospital doesn't get paid for one month of an oncology treatment, it may be out $10,000; but if it doesn't get paid on a gene therapy, the loss could be $500,000 or more. These one-time payments create a level of exposure so high that hospitals may not be willing to take it."

He maintains that "the hospital is in a difficult place, balancing doing what is right for the patient while staying financially viable. On the reimbursement side, hospitals should engage payers and attempt to get information on coverage criteria as early as possible. Once obtained, hospitals should work with the payers to get preapproval, if feasible, for as many patients as possible."

Hospitals Should Take Various Steps

In addition, Schafer recommends that hospitals "should also work with manufacturers on payment options. Hospitals should be frank with manufacturers on the potential for noncoverage and what that may mean for the institution. Hospitals should work with manufacturers to see if alternative payment models, like payments over time or guarantees by the manufacturer if the product is not covered, are possible. On the patient side, the hospital may need to establish a list of potential patients, giving priority to patients in the most serious condition. The hospital may also need to establish criteria for when it will bear risk based on the severity of the patient's condition."

Wong points out that "the CAR-T therapies are a new class of medications. Payers may not completely understand the complete range of cost ramifications, e.g., pre-chemo, harvesting, reinfusion, hospitalization, potential adverse effects (cytokine releasing syndrome), clinical benefit, nor the place in therapy these treatment options represent. Payers need to be educated on the overall process of the CAR-T treatment option….Payers will also need to be educated on how to identify the appropriate population, as well as to provide assistance in the development of the utilization management criteria."

"In my mind," says Wong, "the biggest issue to deal with will not be the medical necessity of the treatment option, but rather the reimbursement for the treatment process, especially to an out-of-network provider. The national payers will more than likely have national network coverage; however, there will be issues with the regional players."

"We'll take the risk of holding the product."

While restrictions exist on what manufacturers can discuss before the FDA approves a product, there is still plenty of room for companies to hold general conversations with payers around coverage and reimbursement, particularly with these innovative and costly treatments.

Schafer points out that "these types of discussions have been complicated by legal and regulatory hurdles that limit the ability of manufacturers to have commercial discussions with payers prior to approval. However, recent revisions in FDAMA [i.e., the Food and Drug Administration Modernization Act] guidance have provided some greater flexibility" *(MAS 11/17, p. 6)*. He recommends that manufacturers consult not only their internal legal departments but also "outside experts on what discussions may be permissible prior to approval. Once manufacturers have a game plan on what topics are permissible, they should ask the payer for the best window of time to have the discussion prelaunch. As payers vary in their drug review schedules and timing, the answer will vary from plan to plan. However, manufacturers should expect that payers will probably want to understand the product usage, estimated numbers of patients who would receive the product and, naturally the approximate cost. Manufacturers will need to determine how much of this information they can or are willing to share."

According to Schafer, other kinds of information payers want include data on a product's efficacy

and safety: "Notably, in what proportion of patients does the product fail? Are there other costs, such as hospitalization or supportive care, associated with the product's use? Is the response durable, or will the patient need the treatment again? Finally, are there potential offsets in future reduced drug use or lower health care resource use due to the outcome of the gene therapy? All of this information helps the payer understand the total cost of care in the disease area and the potential impact on the plan as a whole."

"It is never too soon to educate payers."

"There is no reason for manufacturers to not have discussions with payers prior to the launch of a new medication," maintains Wong. "The only limitation may be the FDA and what they allow to be communicated prior to 'approval.' The more that a payer knows prior to the release of a new drug is always to the benefit of the manufacturer, especially if it is a new novel class of medications, such as the CAR-T, where there is not only a medication, but also the process of harvesting and reinfusing white cells."

"It is never too soon to educate payers," he asserts.

Miller says Express Scripts has "developed relationships" with pharma manufacturers, and the company is "talking to them well over a year prior to a drug's launch." While the firms "never discuss specific prices," Express Scripts will at least "give them an idea of where we are," he says. Express Scripts, he says, is "pleased with discussions" it's had with companies, and he adds that the PBM may begin talks in late Stage II or Stage III clinical trials in the hope that it is "able to influence the thinking" of drug companies.

He notes that "many of these products will be provided through the medical benefit, which is a steep hill" for these manufacturers to climb because they have to "contract with many, many different health plans." According to Miller, "many health plans wait until they have an actual patient before engaging" with manufacturers.

So what might be some of the contracting models that payers and manufacturers will enter into? For payers, Schafer says, "establishing coverage criteria early and communicating it to the provider network is key. The payer should encourage its provider network to seek approval prior to therapy administration, and the payer should review requests in an expedited manner."

In addition, he continues, "the payer and manufacturer should work out a payment arrangement that spreads risk so that hospitals can move forward and treat patients. Some of the gene therapy manufacturers have made headlines for being willing to bear risk if the product doesn't work. This kind of arrangement may make payers more willing to cover therapy earlier, knowing that if the product fails, the payer won't bear the risk. Another option would be for manufacturers to accept payments over a period of time. This allows payers to spread the risk over time. A payment plan arrangement would also be beneficial if it followed the patient when or if that patient switched to another payer. Payers are always concerned about making significant investments in a drug only to have that member leave to another plan. Having the new plan pick up the payment schedule when a member joins would ease adoption for all payers."

Early Commercial Success Is Important

Finding effective approaches that allow appropriate members to access these gene therapies is particularly important in this nascent industry. "Early commercial success of the first gene therapies will be important to encourage more manufacturers to pursue these life-changing agents," Schafer says. "In order for gene therapies to be successful, there needs to be uptake by health systems and coverage by payers. If these new payment models can spread risk in a way that is acceptable to all stakeholders, it may create a path forward for future gene therapies to be covered. There is likely to be a competitive advantage for manufacturers that are willing to be flexible in payment methods by speeding their product's adoption over challengers."

Contact Miller through Jennifer Luddy at Jennifer_Luddy@express-scripts.com, Schafer via Tess Rollano at trollano@coynepr.com and Wong at w2sqgroup@gmail.com. ✧

by Angela Maas

Reality Check: **Diabetes**

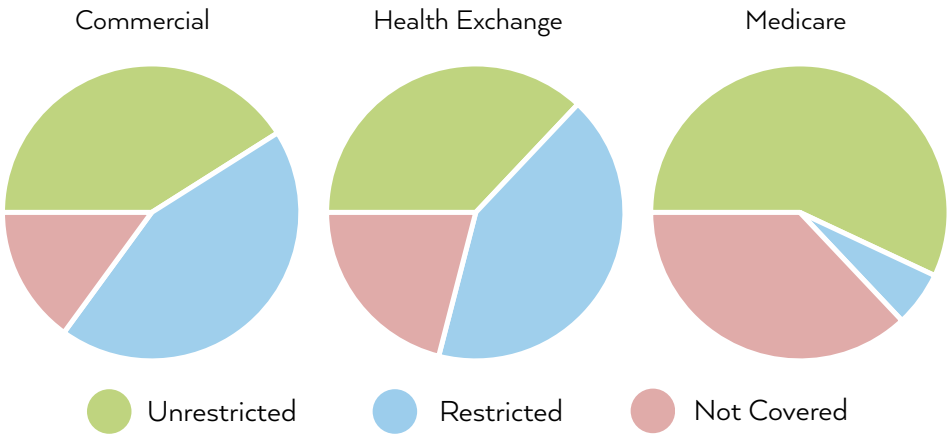
Our Point of View

Diabetes treatments face a complex coverage landscape, specifically within the health exchange marketplace where over half of lives are restricted by a prior authorization (PA) or step therapy. However, Medicare Part D formularies fail to cover products for the greatest percentage of pharmacy benefit lives. Massive PBMs, like CVS Caremark and Express Scripts Holding Co., include several anti-diabetic products on their 2018 formulary exclusion lists, noting mutual preferred alternatives. Certain manufacturers find success in focusing more energy on payer contracting and relationships. Novo Nordisk and Eli Lilly and Co. are the major two heavyweights within this space and fight to promote on the lowest copay tiers.

Coverage

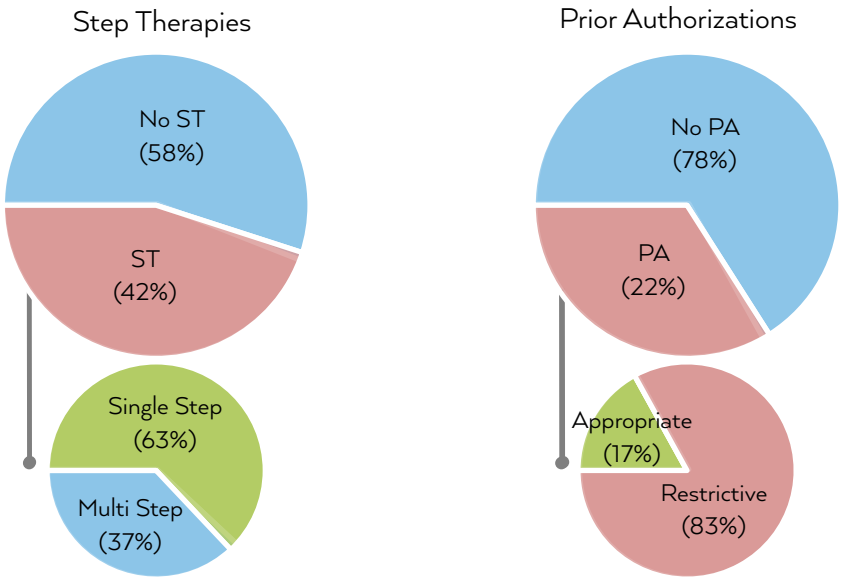
Drugs

Pharmacy benefit reimbursement varies across the major coverage channels for diabetes treatments. Over the past quarter, we see an increased percentage of restricted lives across commercial and health exchange formularies.



Payers

Utilization management for top diabetes treatments in the pharmacy benefit landscape shows the level of restrictive PAs as well as the prevalence of step edits. Over the past quarter, the nature of PA and step-edit policies remained almost totally stable.



DATA CURRENT AS OF Q4 2017

Reality Check: **Diabetes**

AIS Health's View

A year after the first follow-on insulin glargine, Basaglar, from Eli Lilly and Co. and Boehringer Ingelheim Pharmaceuticals, Inc. launched in the U.S. diabetes market, access to the drug among payers is growing rapidly, with half of all U.S. formularies placing it on their first or second tier. Although Basaglar has delivered modest savings compared with originator drug Lantus, payers may see deeper discounts once other follow-on insulin glargines like Merck & Co., Inc.'s Lusdana hit the insulin market. Nadina Rosier, Pharm.D., health and group benefits practice leader for pharmacy at Willis Towers Watson, tells AIS Health that the bottom line is that "the class shouldn't change that much given the introduction of follow-on biologics, since they are viewed as brand-name drugs and don't have significant discounts yet."

Trends From AIS Health

Follow-on Biologic Basaglar Shakes Up the Insulin Market

A year after the first follow-on biologic Basaglar (insulin glargine) from Eli Lilly and Co. and Boehringer Ingelheim Pharmaceuticals, Inc. launched in the U.S. diabetes market, access to the drug among payers is growing rapidly, with half of all U.S. formularies placing it on their first or second tier.

From AIS Health's *Drug Benefit News*

Express Scripts Study Reinforces Importance of Rx Adherence

A new report on diabetes issued by Express Scripts Holding Co. confirms that medication adherence is the way to get the most bang for the buck on improving diabetic outcomes at lower costs.

From AIS Health's *Drug Benefit News*

Studies Show Diabetes Members' Overall Costs, Benefits of Statins

A group of commercially insured members with diabetes cost two-and-a-half times what a similar group without the condition cost, according to a recent analysis of pharmacy and medical claims data. But when members with diabetes took a statin to prevent heart disease per 2013 updated guidelines, their risk for having a cardiovascular event dropped by more than 23%, according to a second study of the same patient population.

From AIS Health's *Drug Benefit News*

Reality Check: **Diabetes**

Key Findings

Market Events Shift Landscape

Within the past couple of years, combination product launches have greatly affected this market basket. Other major market events, like a product being pulled off of the market, mean that competition is dynamic.

Coverage Trends Within Pharmacy Benefit

Products process exclusively under the pharmacy benefit. A comprehensive review of utilization management policies reveals the inconsistencies in PA and step-therapy criteria format across major health plans and PBMs. Due to the diversity of the market basket, from orals to insulins and SGLT2 & GLP-1 inhibitors to combination therapies and DPP-4 inhibitors, the complexity of policies continues to provide challenges to prescribers.

Characteristics

Indications

Type 2 Diabetes Mellitus

Step-Therapy Policies

Step therapies exist for 42% of covered lives in this snapshot. Of those step edits, 37% require multiple product steps.

PA Policies

PA policies exist for 23% of covered lives. When PAs exist, an overwhelming 83% are considered restrictive to the FDA-approved label.

DATA CURRENT AS OF Q4 2017

AIS Health's View

Although follow-on diabetic products have not yet had a big impact on that class of therapies, aggressive payers already are looking at how to adjust coverage to play the competitors off one another. The *Willis Towers Watson 2017 Best Practices in Health Care Survey* showed "that 28% of high-performing, lower-cost employers versus 18% of low-performing, higher-cost employers are evaluating a number of cost and trend management options proactively to promote their use, if the cost is dramatically cheaper," according to Nadina Rosier, Pharm.D., health and group benefits practice leader for pharmacy at WTW. Once Merck's Lantus follow-on biologic comes on the market, she tells AIS Health that in managing the class, "Employers are best to ensure they are evaluating available options for formulary, utilization management and plan design to promote cost effective use of all specialty drugs, including biosimilars."

About AIS Health

The mission of AIS Health — a publishing and information company that has served the health care industry for more than 30 years — is to provide readers with an actionable understanding of the business of health care and pharmaceuticals. AIS Health's in-depth writing covers the companies, people, catalysts and trends that create the richly textured contours of the health care and drug industry.

AIS Health, which maintains journalistic independence from its parent company, MMIT, is committed to integrity in reporting and bringing transparency to health industry data.

Learn more at https://AISHealth.com and https://AISHealthData.com.

About MMIT

MMIT is a product, solutions and advisory company that brings transparency to pharmacy and medical benefit information. MMIT partners with PBMs, payers and pharmaceutical manufacturers from P&T to point of care. We analyze market access trends and market readiness issues, while providing brand and market access solutions to navigate today's rapidly changing healthcare market.

Our team of experts focuses on pharmaceuticals, business drivers, market intelligence and promotional behavior. Our products and services support brands approaching launch, commercialization efforts, pre-P&T market planning, launch strategy and readiness. We partner with hundreds of payers and manufacturers ensuring that our products continually capture and analyze formulary coverage and restriction criteria for more than 98% of all covered lives.

Learn more at https://www.mmitnetwork.com.