RADAR on

Drug Benefits

Business Strategies and Analysis for Health Plans, Employers, PBMs and Pharma Companies

May 13, 2021
VOLUME 22 | NUMBER 9

Subscribers to *RADAR on Drug Benefits* can access articles, infographics and more at AISHealth.com. If you need help logging in, email support@aishealth.com.

House Appears Likely to Vote on Drug Pricing Legislation

Work on drug pricing legislation is underway in Congress, with two House committees holding hearings on the topic in May. The most likely changes are PBM regulation, lowering out-of-pocket costs for Medicare Part D beneficiaries, allowing HHS to negotiate drug prices for Medicare patients, and limiting year-to-year price hikes to no more than the rate of inflation.

While all those policies are on the table, it's unlikely that all of them would make it through Congress. Majority Democrats have few votes to spare, which means party-line legislation would have to pass through the Senate's budget reconciliation process in a blockbuster bill that is mainly focused on a Biden administration priority like infrastructure. However, insiders expect the House to pass some version of legislation based on H.R. 3, the Lower Drug Costs Now Act, which includes Part D reform, drug price negotiation and inflation caps. New PBM regulations similar to those proposed by retired Sen. Lamar Alexander (R-Tenn.) in the 116th Congress, including requirements that PBMs pass through all rebate revenue and disclose all negotiated prices to plan sponsors, are under discussion, according to insiders.

continued on p. 6

Dupixent Gains Share in Atopic Dermatitis, but New Drugs Loom

Dupixent (dupilumab), the first biologic approved for atopic dermatitis (AD), hasn't shaken up treatment of the condition completely even as it steadily gains market share, since the bulk of plans still require patients to try mostly generic topical corticosteroids (TCSs) and topical calcineurin inhibitors (TCIs) first. But more competition could be coming to this category, with the FDA set to consider four new products for AD, including three Janus kinase (JAK) inhibitors.

The oral JAK inhibitors hit a speed bump in April: The FDA extended the review period to early in the third quarter of 2021 for Pfizer Inc.'s abrocitinib for the treatment of adults and adolescents with moderate to severe AD. The agency also extended review to the third quarter of Eli Lilly and Co.'s and Incyte's supplemental New Drug Application for Olumiant (baricitinib) for the treatment of adults with moderate to severe AD, saying it wants to gather additional cost-benefit and safety data.

Meanwhile, the FDA requested additional data on LEO Pharma A/S's biologic tralokinumab, intended for adults with moderate to severe AD, but only on a device component, not on efficacy or safety, the company said in April. The European Union's Committee for Medicinal Products for Human Use recommended approval of tralokinumab in April.

Finally, a topical JAK inhibitor, Incyte's ruxolitinib, was accepted for FDA priority review in February, with a target FDA action date in late June.

Published by AIS Health, Washington, DC. An independent publication not affiliated with insurers, vendors, manufacturers or associations.

"The new oral and injectable therapies may bring new formulary options compared to Dupixent," says Mesfin Tegenu, CEO and chairman, RxParadigm, a pharmacy benefit cost management start-up focused on providing tools and transparency. "Depending upon how these new products are priced, market forces may play a role to bring down the annual cost for Dupixent. However, for any responsible prescriber there's an abundance of generic topical corticosteroids available for treatment."

Efficacy for abrocitinib "appears similar to the existing standard (Dupixent)," according to the latest quarterly Drug Pipeline Insights Report from UnitedHealth Group's OptumRx. "Note that currently approved JAK inhibitors have 'boxed warnings' for serious side effects that may also apply to abrocitinib," the report said. Olumiant, approved for rheumatoid arthritis, carries a black box warning for the risk of infections, malignancy and thrombosis.

OptumRx noted that tralokinumab would offer a novel mechanism of action for AD. "Available evidence is that its efficacy appears more modest than competing existing treatment options like Dupixent," the report said. "Note that tralokinumab, like Dupixent, is given by subcutaneous injection, while newer JAK inhibitors would be oral or creams."

If approved, ruxolitinib would be the first topical JAK inhibitor to treat mild-to-moderate AD in patients ages 12 and older, OptumRx's report pointed out. "Mild-to-moderate is a much larger population than moderate-to-severe, but it is also easier to treat with existing drugs such as Pfizer's topical Eucrisa," the PBM said. "Efficacy for ruxolitinib is promising, but there is currently no data directly comparing ruxolitinib against other AD agents. The topical form may reduce some of the safety concerns associated with oral JAK inhibitors."

The wholesale acquisition cost of Dupixent, from Sanofi and Regeneron Pharmaceuticals, Inc., is approximately $41,000 per year. Sanofi reported in February that Dupixent sales rose nearly 74% in 2020 compared with 2019, and attributed the sales growth to rapid adoption of the drug in children ages 6 to 11. Dupixent was approved in May 2020 for use in that age group. "Dupixent total prescriptions increased 65% (year-over-year) and new-to-brand prescriptions grew 18% despite fewer in-person physician, visits which remain below the pre-COVID level," Sanofi said in its earnings release.

The list price of Olumiant is $2,378.40 per month for 2 mg tablets, or more than $28,500 a year, according to Eli Lilly.

Awareness of Condition Is Increasing

The other recent entrant to the AD category, Eucrisa (crisaborole), a steroid-free topical treatment from Palo Alto, Calif.-based Anacor Pharmaceuticals, Inc., costs around $700 per month, or $8,400 per year.

At Prime Therapeutics, Dupixent is preferred on the PBM's standard formulary as a specialty medication, says April Kunze, Pharm.D., senior director of clinical program development. It is subject to utilization management, including step therapy and dispensing limits, Kunze says, adding, "there has been more awareness to this category, and biologics such as Dupixent have been approved with good efficacy results."

Meanwhile, Eucrisa is preferred on Prime's standard A-Series NetResults formulary with no utilization management in place, Kunze tells AIS Health, a division of MMIT.

According to the Asthma and Allergy Foundation of America, there are approximately 16.5 million adults in the U.S. with eczema, the most common form of AD. In 2018, the Journal

RADAR on Drug Benefits (ISSN: 2576-4381) is published 24 times a year by AIS Health, 2101 L Street, NW, Suite 300, Washington, D.C. 20037, 800-521-4323, www.AISHealth.com.

of Investigative Dermatology estimated overall prevalence of AD in adults to be 7.3%.

The brand-name drugs in the pipeline, if approved, will compete for a small slice of the overall AD patient population, Kunze points out: "According to Sanofi/Regeneron, there are approximately 300,000 adults with uncontrolled moderate-to-severe AD patients in the U.S. that may utilize Dupixent, which is about 5% of the moderate-to-severe AD population. This is the same population that may utilize the oral and injectable biologics that are currently being reviewed by the FDA."

Severity Is Low for Most Patients

"The majority of patients are diagnosed with mild to moderate atopic dermatitis," Tegenu says. "Roughly less than 5% of adults have moderate to severe atopic dermatitis." Patients who require additional treatment following or as an alternative to systemic immunosuppressive therapy may then require a biologic, he points out.

Plans may treat Dupixent and Eucrisa as preferred or non-preferred, and typically require utilization management such as step therapy or prior authorization, Tegenu says.

Kunze notes that, if approved, ruxolitinib cream will be the first topical biologic for mild-to-moderate AD. "The anticipated place in therapy is after first-line treatments but before a systemic biologic," she says. "A utilization management program will be created for ruxolitinib, which will be a separate prior authorization program from other biologics."

The newer agents, while potentially beneficial to a subset of patients, are unlikely to shake up treatment of most patients, according to Tegenu. "Treatment starts with the more conventional options, as there is much more data available and cost is significantly lower," Tegenu says. "Topical corticosteroids and emollients continue to be the mainstay treatment to which other topical therapies are compared to. These options, specifically topical corticosteroids (TCS), have been around for quite some time. Additionally, with TCS agents, there are many different options based on level of potency and formulation that can be selected depending on patient-specific criteria, such as age and body area. TCIs [topical calcineurin inhibitors] are appropriate alternatives for sensitive areas in mild to moderate cases, including the face and skin folds."

There are multiple generic TCS products available in a wide range of strengths. For TCIs, there's pimecrolimus and tacrolimus, both of which are available as generics.

Meanwhile, Tegenu says, "these newer agents are typically reserved for when a patient fails or is not a candidate for the alternative." According to the American Academy of Dermatology, therapy first progresses through topical agents, then through systemic agents, and then to a biologic agent if systemic agents fail. Phototherapy, which generally is covered under the medical benefit, can be considered if topical agents fail, although coverage varies by plan (see infographic, p. 6).

New Entrants Won't Lower Plan Costs

Kunze says some patients may benefit from additional options, but plans may not see much savings. In addition, she suggests that the FDA's delay in approving abrocitinib and baricitinib could impact their sales.

"There is potential to create competition for Dupixent. However, given the current pricing of JAK inhibitors, these may not bring down the overall cost of therapy for atopic dermatitis. Because JAK inhibitors provide an oral option, they may appeal to some atopic dermatitis patients who do not want to administer an injectable like Dupixent. However, considering the JAK inhibitors' extended FDA decision dates and the safety issues surrounding JAK inhibitors, and their potential higher cost compared to Dupixent, they may have a difficult time garnering significant market share."

Contact Tegenu at Mesfin.Tegenu@rxparadigm.com and Kunze via Prime Therapeutics spokesperson Denise Lecher at denise.lecher@primetherapeutics.com. View OptumRx's Drug Pipeline Insights Report at https://bit.ly/3o8VWhu. ✧

by Jane Anderson

PBMs Are Major Bright Spot in 1Q Earnings for Some Firms

For two of the largest diversified health care companies, their PBM divisions were a much-touted highlight in the firms' first-quarter 2021 earnings reports and conference calls.

Cigna Corp. Chief Financial Officer Brian Evanko, during a May 7 conference call with analysts and investors, said the firm's "favorable first-quarter earnings were primarily driven by strong Evernorth performance, favorable net investment income, and favorable prior year medical cost development." Evernorth is Cigna's newly renamed health services division, housing its Express Scripts PBM and other assets.

Adjusted revenues and adjusted income from operations for Evernorth each grew 13% year over year to $30.6 billion and $1.2 billion, respectively, with Cigna crediting "strong organic growth, including growth in retail network and specialty pharmacy services"

and "benefits from the effective management of the supply chain, business growth, and strong performance in specialty pharmacy services."

Evernorth also fulfilled 9% more pharmacy prescriptions year over year for a total of 393 million, and Cigna's pharmacy customer base during the first quarter grew to 101.0 million — an organic increase of 2.2 million year to date — "driven by strong ongoing retention and new sales."

During the question-and-answer portion of Cigna's quarterly conference call, Evanko said Cigna is "really pleased with the strong start to the year in Evernorth," but he encouraged analysts "not to overreact" to the segment's performance. He pointed out that Evernorth's first-quarter 2020 results "did not have contributions from Prime Therapeutics," a Blue Cross Blue Shield-owned PBM that is now using Express Scripts' drug-price negotiation services, so the rest of the year probably won't see a comparable amount of growth.

CVS Sees Growth in Specialty Pharmacy

CVS Health Corp., meanwhile, said that the 3.4% and 2.2% year-over-year increase it saw in overall operating income and adjusted operating income were "primarily due to growth in the Pharmacy Services and Health Care Benefits segments," which include its PBM Caremark and health insurer Aetna, respectively.

For its Pharmacy Services segment specifically, CVS reported that total revenues increased 3.8% year over year to $36.3 billion, citing "net new business, growth in specialty pharmacy, product mix and brand inflation." And the segment's adjusted operating income jumped 27.6% compared to the year prior, "primarily driven by improved purchasing economics and growth in specialty pharmacy."

However, CVS did see a 1% decline in the number of total processed pharmacy claims, which it attributed to "a weak cough, cold and flu season" — a factor that was also a major headwind for the firm's retail business segment.

> **"The integrated value story between medical and pharmacy continues to resonate with our employer groups.**

During a May 4 conference call to discuss first-quarter results, analysts pressed CVS executives about why its PBM business performed so well. President and CEO Karen Lynch said the favorable results were "fueled by strong purchasing economics" as well as "the wrap of our specialty trend programs." She also cited CVS's recent drug trend report, which showed an average trend of 2.9%, adding that the firm's cost-management capabilities are "truly resonating in the marketplace" (see story, p. 5).

"The other thing I would mention…is that the integrated value story between medical and pharmacy continues to resonate with our employer groups, and we have had strong success there," Lynch added.

Alan Lotvin, M.D., president of CVS Caremark, later added that the company is "very aggressive" in touting the benefits of its Specialty Connect and Specialty Expedite programs, which respectively help patients get started on new medications quickly and make it more convenient for them to access their prescribed drugs.

At ***UnitedHealth Group,*** PBM division OptumRx was not among the major highlights of the company's otherwise strong first-quarter financial results. OptumRx revenue and earnings were "relatively consistent year over year and in line with our expectations," Chief Financial Officer John Rex said during UnitedHealth's April 15 conference call to discuss quarterly results. And prescription volume, on an adjusted basis, declined from 339 million during the first quarter of 2020 to 329 million for the same period in 2021 — a result attributable to the surge of script fills during the early days of the COVID-19 pandemic.

Still, "pharmacy care and specialty services continue to grow strongly, in particular home infusion and our community behavioral health pharmacies," Rex added. UnitedHealth President and Chief Operating Officer Dirk McMahon also highlighted the company's medication sourcing program for helping drive affordability. Through that program, "high-cost providers now source drugs at a network specialty pharmacy including OptumRx, or charge market rates only for the drug," McMahon said, adding that "early work on this has generated substantial savings for our customers."

Anthem Touts Greater Integration

Executives at ***Anthem, Inc.***, which has a relatively new PBM in IngenioRx, partially credited "pharmacy product revenue" related to that division for the overall year-over-year increase in operating revenue it reported for the first quarter of 2021. That segment itself saw its operating income rise 12.8% compared with the prior-year quarter to $5.9 million, and its operating margin increased by 20 basis points to 6.9%.

IngenioRx's operating gain was $407 million in the first quarter of 2021, an increase of 16.6% from $349 million in the first quarter of 2020. That "was driven by an out of period adjustment and growth in integrated medical and pharmacy membership," according to Anthem's earnings release.

During the company's April 21 earnings call, CEO Gail Boudreaux specified that the out-of-period adjustment was a "true-up in our specialty pricing," and that "on a run-rate basis, we still feel very good and bullish about [IngenioRx] being in a 6% to 6.5% margin target."

"I think Ingenio has really hit its stride in terms of our business," Boudreaux added.

Humana Plans to Boost Mail Order

Humana Inc. said improved profitability in its Healthcare Services segment, which includes PBM Humana Pharmacy Solutions, was one of the factors that drove its strong first-quarter financial results. That segment reported revenues of $7.2 million in the first quarter of 2021, up from $7.1 million in the prior-year quarter, and its adjusted earnings rose from $319 million to $329 million.

During the company's earnings call on April 28, Chief Financial Officer Brian Kane noted that "we continue to pursue pharmacy initiatives that we expect to further increase mail order penetration as the year progresses."

Finally, pharmacy services weren't a major point of discussion during ***Centene Corp.'s*** April 27 earnings call, although the company did mention that its revised 2021 financial guidance factors in delays for California's and New York's plans to carve out pharmacy benefits from their Medicaid managed care contracts.

Chairman, President and CEO Michael Neidorff also addressed a lawsuit filed by Ohio, which claims Centene overcharged the state for PBM services (see brief, p. 8), saying the firm "has been clear that we maintain the claims to be unfounded." ✧

by Leslie Small

CVS Health Drug Trend Report Highlights Specialty Spending

In its 2020 Drug Trend Report, CVS Health Corp.'s Caremark PBM said its overall drug trend increased by 2.9% in 2020 and that 34% of its clients saw their pharmacy benefit spending decrease.

According to the report, specialty drug costs were the biggest concern. In fact, specialty treatments accounted for 52% of pharmacy spending in 2020, with 90% of spending concentrated on just five therapeutic categories. Despite that, the report asserts that "more than 40% of [Caremark] clients had single-digit specialty trend," and "18% of [Caremark] clients had negative specialty trend."

The PBM also reported that drug utilization for its clients increased by 1.7% and prices increased by 1.2%. For plans Caremark described as "tightly managed," trend was 0.6%, and the PBM claimed per member per month costs were $10 lower than the overall cohort. Further, echoing Cigna Corp.'s Evernorth Drug Trend report *(RDB 4/8/21, p. 3)*, CVS's report quantified how dramatically the pandemic caused medication utilization to plummet in April 2020.

Price Claims Are Hard to Verify

Elan Rubinstein, Pharm.D., principal at EB Rubinstein Associates, tells AIS Health, a division of MMIT, via email that the claims Caremark makes in the report are hard to verify.

That rebates were included in the pricing data "makes me uneasy about interpreting the report's dollar claims," Rubinstein writes. "There is zero drill-down on information provided in the report," he adds.

"I find the CVS report uninformative with respect to sole source brands and specialty drugs, which represent the bulk of drug spend even while representing a small fraction of utilization as well as of patients using the drug benefit," he continues.

Rubinstein writes it is "more useful if you consider evaluating the CVS drug trend report together with the CVS Health Trends Report.

The latter suggests CVS's competitive market advantage as an integrated company is more important to the business, "compared to a standalone drug chain or PBM or specialty pharmacy — particularly with respect to increasingly common, super-expensive pharmaceutical and biopharmaceutical therapies," Rubinstein says.

In its Health Trends Report, CVS estimates that "just 11 conditions could add an additional $45 billion to health care costs over the next five years."

Vertical Integration Is a Selling Point

More to the point, Rubinstein points out that CVS has pitched the vertical integration of Caremark with Aetna's health benefits business as a selling point to plan sponsors in recent years.

"I wonder if, with respect to branded pharmaceuticals and biopharmaceuticals, interventions made possible by a high level of integration will increasingly differentiate companies like United/Optum[Rx], [Cigna Corp./Express Scripts] and CVS [Health Corp.]/Aetna — which together already dominate the PBM market — from competitors," he writes.

Read the Drug Trend Report at https://bit.ly/2RPg7Fn and the Health Trends Report at https://bit.ly/2QbZOlo. Contact Rubinstein at elan.b.rubinstein@gmail.com. ✧

by Peter Johnson

Congress Mulls Drug Price Bills

continued from p. 1

"It appears that House leaders have started to map out what their next steps are on health policy, and they've kind of put some of the more aggressive coverage policy stuff like a public option on the back burner," Shawn Gremminger, the director of health policy for the Purchaser Business Group on Health. But he says he's "bullish" on drug pricing reform making real progress.

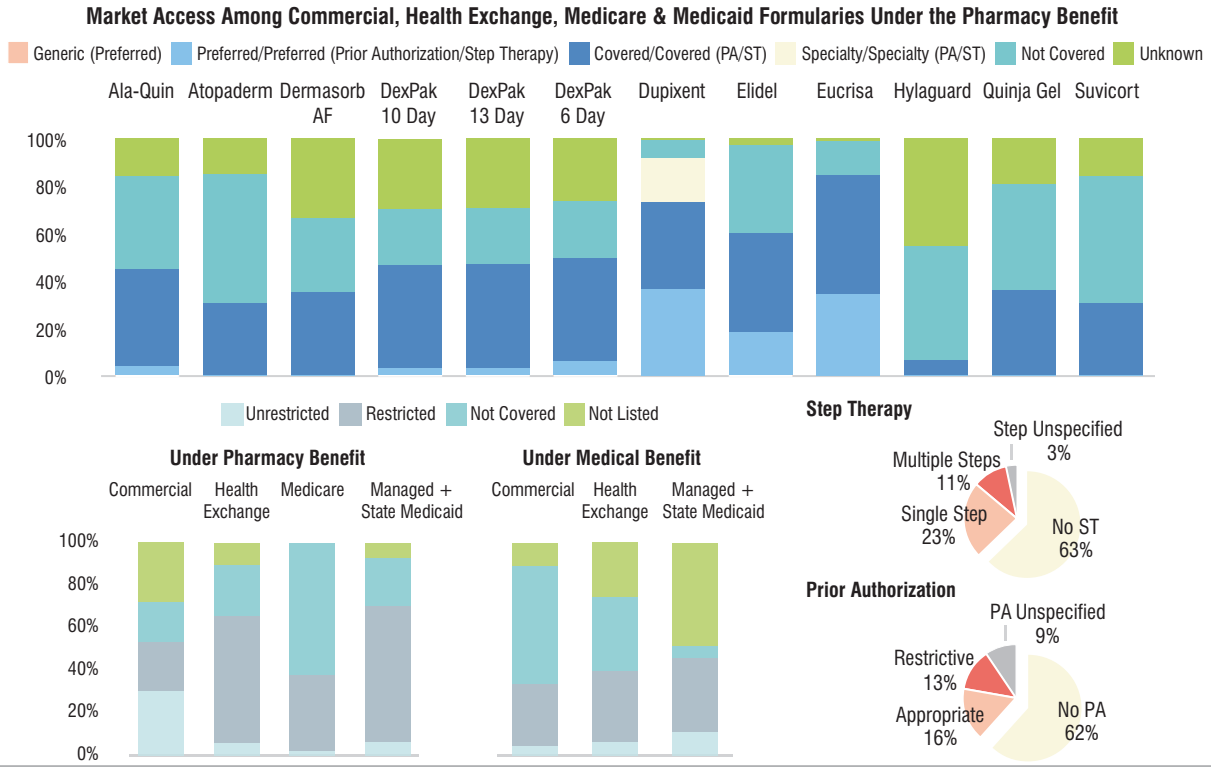
"At least on the House side, it appears it's going to be something that looks close to H.R. 3. On the Senate side, I wouldn't even want to hazard a guess on what it's going to look like. It probably would not be as aggressive as H.R. 3, but may include some of the same overall contours," Gremminger tells AIS Health, a division of MMIT. He expects the House to have a floor vote in "a month or two." But he says the Senate won't take a drug pricing measure under consideration until late summer at the soonest: "On the Senate side, they're also very serious about passing a major drug bill this year. But they're a bit further behind."

House leadership is focused on passing H.R. 3, which is sponsored by Speaker Nancy Pelosi (D-Calif.) and

Current Market Access to Atopic Dermatitis Medications

by Jinghong Chen

The FDA in February accepted a New Drug Application under priority review for Incyte Corp.'s ruxolitinib cream for the treatment of atopic dermatitis. Meanwhile, there are currently more than 10 agents in Phase III trials for this indication. Among the medications that are on the market, Sanofi and Regeneron's Dupixent (dupilumab) and Pfizer Inc.'s Eucrisa (crisaborole) are competing for preferred status after topical corticosteroids, topical calcineurin inhibitors and phototherapy. Most medications are covered under the pharmacy benefit, with the exception of Dupixent. More than half of payer pharmacy benefit formularies do not require step therapy or prior authorization for atopic dermatitis medications.



NOTE: Under the pharmacy benefit, the total covered lives under commercial, health exchange, Medicare and Medicaid formularies are 170.0 million, 11.7 million, 47.8 million and 69.8 million, respectively. Under the medical benefit, the total covered lives under commercial, health exchange, Medicare and Medicaid formularies are 168.4 million, 11.7 million, 49.5 million and 69.8 million, respectively.

SOURCE: Managed Markets Insight & Technology, LLC database as of May 2021.

Rep. Frank Pallone (D-N.J.). Pallone chairs the Committee on Energy and Commerce, which discussed the bill on May 4. In his opening statement, Pallone emphasized that the bill is Democratic leadership's preferred solution to the drug pricing issue.

"H.R. 3 is the comprehensive solution this country needs to fix our broken market for prescription drugs," Pallone said.

"It certainly seems likely that it [H.R. 3] will get a House vote because it has the support of leadership, and all the people who have the authority over the issue in the House," says Ann Marie Breheny, senior legislative adviser for Willis Towers Watson. "The question is what happens in the Senate."

Senate's Deliberations Will Take Longer

There, Breheny says, the conversation is not specific to H.R. 3. Rather, following President Joe Biden's April 28 address to a joint session of Congress, in which he called for fast action on prescription drug prices, "there were a few folks in the Senate who said, 'We are going to try to pass prescription drug legislation on whatever vehicle we can work on.'"

Breheny says that even though there is support in both parties for drug pricing reform, she believes a budget reconciliation bill is most likely since it can pass the Senate with a simple majority.

"At this juncture, it seems more likely that it would be something that would that they'd want to do in reconciliation," she says. "Prescription drug pricing is one of those issues where everybody agrees you need to do something about it, but it's hard to get people to agree what it is exactly you need to do about it. There was a lot of discussion in the last week or so — and a lot of bipartisan conversations last Congress — but just not enough bipartisan consensus on how to move forward. And I don't think that calculation has changed. It's going to be hard to get 60 votes for any one approach."

But there are no guarantees that a bill will make its way out of the House. Breheny referenced a letter signed by moderate Democrats calling for a bipartisan drug price reform bill, which stirred up doubts that H.R. 3 could pass the House. The letter, signed by 10 centrist members of the Democratic caucus, says that "we must garner bipartisan, bicameral support, with buy-in from a majority of Americans and stakeholders in the public and private sectors."

> **"Prescription drug pricing is one of those issues where everybody agrees you need to do something about it, but it's hard to get people to agree what it is exactly you need to do about it.**

Breheny says Part D reforms are the most popular component of H.R. 3 among members of Congress. So does James Gelfand, senior vice president for health policy at the ERISA Industry Committee. However, he observes that limiting out-of-pocket costs for Part D beneficiaries won't actually fix the problem of rising drug prices.

Popular moves like capping out-of-pocket costs for Part D members "do not address the underlying costs of drugs. They simply make someone else pay the unreasonable costs," Gelfand says. "And if that's if that someone else is your employer, that just means it's going to be built into your premium." Ultimately, "that probably encourages the drug companies to keep doing what they're doing. So it probably makes it so you get more of those high costs."

Breheny has similar concerns.

"How do you structure something in a way that addresses the costs without just shifting them?" she says. "If you just do things that affects Part D on its own, does that affect the pricing of the drugs systemically and how the costs are determined? Does it just encourage cost shifting onto payers who are not in Part D?"

Breheny says that H.R. 3 does "attempt to try to address that by giving the private payer the opportunity to use [Medicare] negotiated prices."

H.R. 3 also includes provisions that would prevent drug companies from charging Medicare for annual price increases that exceed the rate of inflation in the Consumer Price Index. Gelfand would like to see that provision extended to the commercial insurance market as well.

Employers Call for Inflation Peg

"We need a pretty substantial change to the bill in that section, to ensure that we can actually be protected in the same way that Medicare is going to be protected," Gelfand says.

Meanwhile, PBM discussions are not yet in the foreground. But Gremminger says his perception is that many members of both parties and both chambers are willing to consider PBM legislation.

"On PBMs, we have already identified a Senate Republican champion who would like to introduce legislation. At this point, our focus is finding a Senate Democratic companion who would be willing to do it," he says. Gremminger declined to identify the senator, but said the person is "a very conservative Republican."

"When I look at the other people who are on the PBM [regulation] train, it's a lot of progressive Democrats as

well. I'm hopeful that we'll have a real strange bedfellows kind of pair when we get this introduced," Gremminger says.

"At the end of the day, PBM reform can pass without prescription drug reform," Gelfand says.

"I think the PBM reform remains something that seems pretty likely, in large part because of the politics around it are more bipartisan," Gremminger adds.

"I think it is easier to get across the finish line," he says. "The more aggressive stuff that House and Senate Democrats are talking about does not necessarily enjoy bipartisan support. It's just going to be a bigger lift."

Read H.R. 3 at https://bit.ly/3w2AvBK and watch the hearings at https://bit.ly/3hgSkJ4 and https://bit.ly/3eF4p96. Contact Breheny via Ed Emerman at eemerman@eaglepr.com, Gelfand via Kelly Broadway at kbroadway@eric.org and Gremminger via James Chisum at james@millergeer.com. ✧

by Peter Johnson

News Briefs

✦ ***Officials in as many as seven states plus the District of Columbia are now probing PBM business practices, The Wall Street Journal reported on May 11.*** One of those states, Ohio, has filed lawsuits against Cigna Corp., UnitedHealth Group and Centene Corp. that accuse the companies and their PBM divisions of overcharging the state, and it is also moving to a single-PBM system *(RDB 3/11/21, p. 1)*. In addition to Ohio's probe, the Journal found that PBM investigations are ongoing in Arkansas, D.C., Georgia, Kansas, Mississippi, New Mexico and Oklahoma. Several states are working with the same law firm that is filing suits on behalf of Ohio. Read more at https://on.wsj.com/3bkkFdE.

✦ ***When it comes to patients' exposure to rising drug list prices, prescription drug benefit design makes a big difference, according to a study recently published in JAMA Network Open.*** The study examined pricing data from January 2015 to December 2017 for 79 brand-name drugs as well as a national insurance claims database. Among that commercially insured cohort, roughly half had fixed copayments and "were insulated from increases in list prices." But the other half of patients had prescription drug benefits that included deductibles or coinsurance "and, in that cohort, out-of-pocket costs increased when manufacturers increased list prices," the study found. What's more, "changes in net drug prices accounting for manufacturer rebates were not correlated with changes in patient out-of-pocket spending, suggesting that increasing rebates offered by manufacturers to partially offset list price hikes are not being directly passed on to patients, even if they limit increases to total drug spending." Read more at https://bit.ly/3o6ZwsF.

✦ ***The Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP) on May 12 voted to recommend Pfizer Inc./BioNTech's COVID-19 vaccine for children ages 12 to 15.*** The move comes just two days after the FDA expanded the Pfizer/BioNTech vaccine's emergency use authorization to include the 12-15 age group; previously the EUA applied only to individuals age 16 or older. The American Medical Association issued a statement soon after ACIP recommended the vaccine for adolescents, with AMA President Susan R. Baily, M.D., writing that the move "brings us one critical step closer to our nation's goal of achieving widespread vaccination among the U.S. population." The trade group also urged the federal government to "ensure physician practices have an adequate supply of COVID-19 vaccines and encourage manufacturers to begin offering the vaccine in smaller shipments with fewer doses per vial so physician practices can accommodate patient demand while avoiding unnecessary vaccine waste." Read more at https://bit.ly/3tIhqmP.

✦ ***Pfizer has acquired privately-held Amplyx Pharmaceuticals, a firm that is developing a treatment for drug-resistant fungal "suberbugs."*** At present, only three such drugs exist, and more fungi are developing resistance to existing treatments. Terms of the deal were not disclosed. Read more at https://bwnews.pr/2R6kITF.

✦ ***CORRECTION:*** Boston-based Akili Interactive manufactures EndeavorRx, a digital therapeutic device approved by the FDA to treat ADHD. An article in the April 22 edition of Radar on Drug Benefits incorrectly stated that EndeavorRx was manufactured by Canadian company Ehave, Inc.