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Pharma's Concerns Mount Months after the Chevron Decision

(Source: An article by Amy Baxter for PharmaVoice)

The U.S. Supreme Court in June overturned the Chevron deference, which previously gave agencies the final say in how ambiguous federal laws are interpreted and turned the power over to the courts.

The landmark decision could have widespread implications in pharma, stripping away some authority from both the U.S. Food and Drug Administration (FDA) and the Center for Medicare and Medicaid Services (CMS). It also opens the door for pharma companies to legally challenge policies and regulations, such as the U.S. Inflation Reduction Act (IRA) and a recent lab-developed test rule.

The shift has cast more uncertainty into a tough regulatory environment, which is why the pharma industry may be taking a "wait-and-see" approach in the fallout, said Jesse Mendelsohn, senior vice president at revenue management company Model N.

This means more uncertainty going forward as companies navigate this new legal landscape. The decision could expose even day-to-day decisions by the FDA to legal challenges. Patent issues, regulatory efforts and R&D focus are areas where the industry might have to reconsider their strategic positions, according to a report published by the law firm Buchanan, Ingersoll & Rooney.

"While companies may now enjoy more success in their litigation efforts against the FDA, the inevitable result will be a period of uncertainty as FDA, regulated industry and the courts navigate the next steps in a post-Chevron legal world," Buchanan experts wrote in the report.

The drug development process could also be further muddled if pharma companies launch challenges against the FDA's authority, Mendelsohn said.

However, the industry may not want to rock the boat when it comes to the established drug development and approval process. Already, the pathway for a drug from research to approval can be as long as 10 to 15 years, according to the National Institutes of Health. And in recent years, the cost to develop a new drug ranges between US$1 billion to US$2 billion, per U.S. Congressional

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In Brief...

- **Walgreens Boots Alliance** has sold all of its remaining unemcumbered shares of **Cencora** common stock for proceeds of US$818 million, which is subject to a concurrent share repurchase by Cencora of US$250 million. The company's ownership of Cencora's common stock has decreased from 12% to approximately 10%. Proceeds to Walgreens Boots Alliance will be used primarily for debt paydown and general corporate purposes, as the company continues to build out a more capital-efficient health services strategy rooted in its retail pharmacy footprint.
- Five months after the U.S. FDA rejected **Regeneron's** bid for accelerated approval of its T-cell engager *odronextamab*, the European Union has signed off on the treatment for two types of blood cancers. In winning the nod from the European Commission for relapsed or refractory follicular lymphoma (FL) and for relapsed or refractory diffuse large B-cell lymphoma (DLBCL), *Ordspono* becomes Regeneron's first approved bispecific antibody. The endorsement covers patients who have undergone two or more lines of systemic therapy.
- A growing number of studies suggest GLP-1 receptor agonist drugs could slow progression in diseases such as Alzheimer's and Parkinson's diseases, potentially opening another huge market for the class of drugs beyond type 2 diabetes and obesity. Numerous new academic studies have been presented at the ongoing *Alzheimer's Association International Conference*, including a trial investigating **Novo Nordisk's** older GLP-1 product *Liraglutide*, marketed as *Victoza* for type 2 diabetes and *Saxenda* for obesity.
- The Biden administration announced that it will resume offering free at-home COVID-19 tests to American households in late September as the virus has gained a stronger foothold in the U.S. this summer. Americans will soon be able to use

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NACDS Reiterates Fight Againt PBMs at its 2024 TSE Expo

(Source: An article by Nigel F. Maynard for Drug Store News)

NACDS President and CEO Steven C. Anderson again reiterated pharmacy's important role in the nation's national health care system and delivered straight talk about what this industry is facing.

"Too often, the middlemen in the system—the pharmacy benefit managers—operate in secrecy," Anderson said on day two of Total Store Expo in Boston. "They reimburse pharmacies below their costs, and steer patients to the pharmacies they own all while inflating patients' costs and interfering with their care."

Similarly, Anderson expressed frustration over barriers to the full potential of retail health. "We know how much more retail health could do for America. But there are stodgy scope-

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Pharma Concerns *(cont'd.)*...

Budget Office estimates. Legal challenges to that process or how the FDA makes decisions could hinder the pathway to approval, extending timelines and adding costs.

The Chevron decision came as the CMS navigated Medicare drug price negotiations with drugmakers as part of the IRA. The CMS and drugmakers went back and forth throughout the summer before the final negotiated prices were published earlier in August.

Drugmakers have voiced opposition to the IRA's provisions since the law was on the table, and several of the affected pharma companies launched lawsuits to attempt to kill the negotiation program. So far, drugmakers have been unsuccessful in court, but the Chevron decision adds another layer of uncertainty to the dynamic.

"There were already a host of lawsuits trying to attack the IRA on constitutional and other grounds, and those mostly have not seen much [success from a] manufacturer's perspective," Mendelsohn said. "I think there is a general wait-and-see approach, not just with the IRA for manufacturers, but guidance in general."

Several top pharma executives have criticized the IRA's overall impact on the industry, with Bristol Myers Squibb CEO Christopher Boerner referring to the negotiation program as "arbitrary price setting by the government," in the company's most recent earnings call. The CMS stated the negotiations were "genuine" and "thoughtful," with an agreement on price reached for five of the 10 drugs selected, while the other half accepted CMS's final written offer. Moving forward, it's possible drugmakers won't attack Medicare's new ability to negotiate drug prices in Part D, but rather how the negotiations are conducted.

"Negotiating prices and rebates is kind of second nature to pharmaceutical manufacturers — they do it all day long with payers and providers," Mendelsohn said. "The impression was that this interpretive guidance was more compulsion than negotiation, and with Chevron no longer the rule of the [land], it opens up that interpretive guidance to the judicial review."

In this era of uncertainty, Congress could pass more laws to clarify the IRA provisions, as it has done in the past for other major healthcare reforms, such as the Affordable Care Act.

"Congress still has the capability right now when it comes to gray areas and challenges of the IRA by passing another piece of legislation that will clarify those things," Mendelsohn said. "You will likely see more lobbying for clarity to come from the Congress."

However, with the presidential election only months away and a gridlocked Congress, it's unlikely anything will happen quickly.

NACDS *(cont'd.)*...

of-practice laws in some states," he said. "Payment for services can be inadequate, or non-existent. There is protectionism by some groups of healthcare providers, and healthcare economics have made it hard to fully leverage our industry's scale."

But Anderson was hopeful and about progress on both of these issues.

"I am here to tell you that this association is firing on all cylinders," Anderson said. "Together we're getting after these challenges and that is a credit to the engagement and expertise of the NACDS Board of Directors and membership—and a credit to the passion and proficiency of the NACDS staff."

The association's call for *"PBM Reform Now"* is reaching the tipping point of awareness in the nation's capital and in the states, Anderson said.

"When we started talking with government about DIR fees and PBM reform…eyes would glaze over," he said. "It was simply too complicated. But now, as understanding deepens, eyes light up, voices rise, and the call for PBM reform grows louder and more fervent. Today, Republicans and Democrats in the U.S.Congress, and in the state legislatures, understand what it means for their constituents, communities, employers, and pharmacies when PBM middlemen profit at their expense."

The ball is in Congress's court to get PBM reform done now, Anderson said.

Additionally, Anderson discussed NACDS' continued push for federal provider status legislation, the *Equitable Community Access to Pharmacist Services Act (HR1770/S2477),* alongside the *Future of Pharmacy Care Coalition*. The bipartisan bill would ensure that seniors in Medicare have access to pharmacy services.

In Brief (cont.)

COVIDtests.gov to request four free tests. The tests will be able to test for the COVID variants that are currently spreading, most of which are the mutations of the highly contagious omicron variant JN.1.

- Despite setbacks, **Pfizer Inc.** believes its oral GLP-1 agonist *danuglipron* remains in a competitive position versus rivals. During Pfizer's Q2 sales and earnings call on July 30th, CEO *Albert Bourla* said the company hopes to move a new once-daily formulation of *danuglipron* into registration-enabling trials quickly if dose-optimization studies planned for the second half of 2024 yield positive results for the drug's efficacy.
- The consumption of antibiotics in Japan surged over 20% year on year in 2023, showing a rebound from the COVID-19 pandemic years, according to survey data released on August 6 by the **National Center for Global Health and Medicine (NCGM)**. The volume of antibiotics used in 2023 was 17.6% lower than in 2013 and was up 22.3% compared to 2022. It was also up 17.5% from 2020, the final year of the first *National Action Plan on Antimicrobial Resistance (AMR).*
- An adult man dubbed *"The Next Berlin Patient"* has been declared the seventh person to be cured of HIV. The patient was diagnosed with HIV in 2009 and then later developed acute myeloid leukemia. In 2015, the clinical team decided the patient needed a hematopoietic stem cell transplant in his bone marrow to treat his cancer and began searching for donors with this rare genetic mutation known as the homozygous delta-32 CCR5 mutation, as it has shown to provide natural resistance to HIV. After treatment, the patient discontinued antivirals in 2018 and has shown no signs of the virus to date.

(Sources: CNBC, Drug Store News, FiercePharma, Pharma Japan and Scrip Citeline)