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## How The U.S. Election Could Affect the Pharma Industry

(Source: An Article by Jessica Merrill for Scrip)

The outcome of the US presidential election in November, whether Democrat president Joe Biden wins the election or former Republican president Donald Trump, is bound to result in continued emphasis on drug prices and health care spending.

Pharmaceutical executives and industry experts discussed implications of the upcoming election for pharma during the *Financial Times US Pharma & Biotech Summit* in May. The pharmaceutical industry is expected to remain a political punching bag regardless of whether Democrats retain power in the White House or Republicans regain the oval office. President Biden triggered the wrath of many in the industry with the passage of the *Inflation Reduction Act (IRA)*, which includes a landmark Medicare drug price negotiation program. Should Biden win the 2024 election, the result could be more emphasis on drug price negotiations through expansion of the IRA, as well as other initiatives.

Either way, drug pricing is expected to remain a political pressure point.

Likewise, many pharma executives and experts at the Summit said both Biden and Trump pose risks to pharma. While Biden could try to expand initiatives under the IRA, Trump was an advocate of international reference pricing.

Trump, meanwhile, isn't a refuge for the pharma industry. The former president has showed a willingness to implement drastic new drug pricing policies from 2017-2021 when in office, including an attempt to implement a reference pricing policy tying US drug prices to international prices.

"There are risks no matter who wins the election," said Darius Lakdawalla, Quintiles chair in pharmaceutical development and regulatory innovation at the University of Southern California. Another Biden presidency would involve the evolution and strengthening of the IRA and the new Medicare drug price

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## In Brief...

- ♦ Japan's top four wholesalers saw growth in both their combined sales and profit in FY2023 through March, with three of them topping 1% in operating margins, a mark that is considered essential to maintain stable operations, according to a Jiho tally. Performance of the four companies (**Toho Holdings, Suzuken, Medipal and Alfresa**) was stable throughout the year with total combined revenue of ¥8,559.4 billion (US\$ 54.8 billion), up over 5% year-over-year, and a combined operating profit growing 11.7% to ¥100.4 billion (US\$ 643.46 million.)

- ♦ **Gilead Sciences Inc.** is piloting a partnership with community oncology centers aimed at shouldering much of the legwork that will allow patients to receive *CAR-T* therapy closer to home instead of requiring them to travel to academic medical centers. The CA-based drug maker introduced the partnership with **Tennessee Oncology** in the first quarter of 2024 and expects to start seeing positive impacts of their efforts by the end of 2024. The idea is to enable patients to receive *CAR-T* cell therapy in their communities and also expand the number of eligible recipients.

- ♦ **Pfizer Inc.** launched its respiratory syncytial virus (RSV) vaccine *Abrysvo* in Japan for both maternal immunization and use in people 60 years of age and older. The vaccine was approved in Japan in January for the prevention of RSV-associated lower respiratory tract disease (LRTD) in infants through immunizations for pregnant women. Later in March, it

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## Pharma Holds US\$1 Trillion to Spend on Biotech Innovation

(Source: An article by Analee Armstrong for FierceBiotech)

According to a new report published by EY, pharmaceutical companies have amassed a record US\$1 trillion to deploy on new biotech innovation deals and are waiting for the Federal Reserve to lower interest rates. Currently, that is tenuous, with the market mostly betting that there will be one decrease in the second half, but the rates are expected to remain the same in the near term, according to the CME FedWatch Tool. But, if the pressure is relieved, biotech is poised for a comeback, according to EY's latest *Beyond Borders* report published June 1st.

"Despite the Federal Reserve delaying action on interest rates, biotechs still have grounds for continued cautious optimism," said Arda Ural, Ph.D., EY Americas life sciences sector leader, in a statement.

"The combination of record-level dealmaking capacity seen throughout 2023, firepower of big pharma and the healthy innovation capacity of the sector, including possibilities from artificial intelligence, will ultimately help the biotech sector to not only survive but thrive in the mid- to late-term."

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## Election (cont'd.)...

negotiation program, while with Trump as president, some form of reference pricing is “moderately likely,” Lakdawalla continued. “That’s probably a bad idea, but that doesn’t mean it won’t be pursued.”

GSK head of public policy, Harmeet Dhillon, said the company is thinking about the possibility of reference pricing returning to the forefront in its strategic planning.

Institute for Clinical and Economic Review (ICER) president and CEO, Sarah Emond, also cautioned industry about the potential pitfalls of a Trump presidency. “It’s unlike the olden days when you could expect a Republican administration to come in and be very business friendly,” she said. “We know from his first administration that he was trying to do some aggressive policy changes that would address the drug prices, and so I would expect that would be on the agenda again.”

Some pharmaceutical representatives speaking on panels at the FT conference said they want to see political attention turn more to other stakeholders in the health care sector, like pharmacy benefit managers (PBMs), the middlemen between drug companies and insurers, who have long been the target of industry.

Industry has, for many years, advocated in favor of rebate reform to address one of the troublesome issues in the US reimbursement system, in which drug makers often set high list prices that are offset using rebates to negotiate for formulary placement. The delta between list prices and net prices has grown over the last decade, confounding traditional market dynamics.

The Trump administration investigated rebate reform under its pricing blueprint but abandoned plans when the Congressional Budget Office determined it would be too costly to Medicare.

EMD Serono senior VP-head of global healthcare government and public affairs Terri Stewart said she has seen increased interest on Capitol Hill in digging into the deeper complexities in the system around drug prices.

“I think people want to actually know where the money is going,” she said. “I think people are coming to the realization it very much matters and that they care about it.”

“The other major policy element that I think is rather important is this idea that what is being charged as a service is being for that service, not linked to the price of the drug.”

The service is not more expensive because the drug is more expensive,” Stewart said.

## Pharma Holds (cont'd.)...

The pharma industry is hunting to replace US\$300 billion worth of products that are losing patent exclusivity, meaning companies need innovative new therapies from biotechs.

EY noted the tough two years of financing constraints have pushed biotechs to institute massive layoffs and restructurings. But innovation has remained robust, according to the report, with the FDA approving 80 novel biopharma products in 2023, one of the highest totals ever.

“With the looming patent cliff for big pharma and uncertainty around the [Inflation Reduction Act], faith in innovation will be one of the key pillars in biotechs’ strategies for continuing recovery from the tough times experienced in 2022 and 2023,”

said Rich Ramko, EY U.S. biotech leader. “For now, financing is still catching up, and capital access remains an issue for many companies in the sector. However, biotechnology remains an innovation-driven industry, and innovation is thriving.”

While mRNA vaccines reigned during the pandemic years and autologous cell therapies were at the forefront, cardio-metabolic products like GLP-1 receptor agonists have taken center stage, along with radiopharmaceuticals and antibody-drug conjugates.

Going forward, EY sees IPOs returning on a selective basis below the historical average.

“Venture funding is anemic, the follow-on financings appear to have improved over the 2022-2023 period, yet at suppressed valuations. As a result, our analysis suggests that almost a third of biotechs do not have sufficient cash to sustain their operations over a year,” the firm said.

Venture financing was flat in 2023 at US\$18.9 billion, dropping from the pre-pandemic high of US\$47.5 billion. Early-stage venture investment dropped 8.7% in 2023 compared to 2022, bringing in US\$12.48 billion for early-stage assets.

Instead of M&A, pharma companies have been utilizing cash for alliances since the COVID-19 pandemic. Companies committed a total of US\$125.3 billion in potential value to partnerships in 2023. These deals provide lower-risk access to innovation, EY said. But M&A is on the rise, with a flurry of activity to start the year.

## In Brief (cont.)

earned additional indication for the prevention of RSV infection in adults aged 60 and above.

- ◆ As **Merck’s** blockbuster *Keytruda* approaches its 10-year anniversary on the market, the company seeks to partner with **Moderna** on a vaccine, called *mRNA-4157*, which has shown results from a mid-stage trial of improved survival of three years in patient with melanoma when given with *Keytruda*. This could pave the way for broader use of the vaccine in multiple tumor types like its *Keytruda* predecessor, which now holds 39 indications in 17 tumor types. When combined, the two drugs work in different way to spur a patient’s immune system into action against cancer cells.

- ◆ In the first personal injury case that has gone to trial over the drug *Zantac*, a Chicago jury has rejected the claim that the heartburn drug caused the plaintiff’s colon cancer. The plaintiff, who was seeking US\$640 million for suffering, took the drug daily from 1995 to 2014. The results of the case could have broad implications as thousands of lawsuits have yet to be decided.

- ◆ **Rite Aid** is reportedly close to reaching a deal on a post-bankruptcy financing package, with a group of lenders preparing to provide interim financing while the company remains in Chapter 11, according to attorneys. Rite Aid received court approval in late March to begin voting on a bankruptcy plan that would eliminate US\$2 billion in debt and relinquish the company's equity to a group of lenders including investment funds **Brigade Capital** and **HG Vora**. Rite Aid has struggled to finalize some of the deal's details, delaying its planned exit from bankruptcy by over a month, the report noted.

(Sources: Drug Store News, Fierce Pharma, Pharma Japan, Pharma Voice, and World Pharma News)