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Challenges Mount for Vaccine Makers

(Source: An article by Amy Baxter for PharmaVoice)

Vaccine makers are up against unique and challenging headwinds. On the one hand, technologies like mRNA have offered breakthroughs for tackling infectious diseases. Conversely, market uptake and sales growth for several new shots have been sluggish in the last year.

Now, with Robert F. Kennedy Jr., a critic of vaccines, sworn in as the new head of the U.S. Department of Health and Human Services, drugmakers are also facing fresh regulatory uncertainty.

Recent earnings reports from pharma's largest companies underscore this challenging environment. But while drugmakers face issues like increased vaccine skepticism, they're also keeping the R&D wheels turning and gearing up for potential wins in 2025. Here's what end-of-year reports from some of the largest vaccine makers reveal about the industry's upcoming challenges.

Vaccination rates are falling broadly across disease areas. Among young children, the divide in vaccination rates has fallen along political lines, with kindergartners from some states showing higher rates of vaccine exemptions, The New York Times reported in January of 2025.

Flu vaccination rates for the 2024-2025 season are also well below those from the previous three years, according to the Centers for Disease Control and Prevention (CDC) data. The trend is happening while the U.S. faces its worst flu seasons since 2009, with at least 29 million illnesses reported by the CDC.

However, not every company has been hit by the downturn in flu shots.

Sanofi, the largest influenza vaccine maker, reported that global sales for its flu jab were slightly down for the year, although 2024 was a particularly strong year for comparison, CEO Paul Hudson said during the company's earnings call. Sanofi's vaccine portfolio was also buoyed by uptake in what's become a complex market for RSV. Overall, the company's vaccine sales rose 13.5% during the year, mostly driven by European sales of *Beyfortus*, its RSV antibody approved for babies.

The new shot is among a swath of new RSV drugs that have debuted over the past few years, including a handful approved in the U.S. since 2023. But the breakthrough has not led to runaway sales for drugmakers amid the declining vaccination trend.

GSK's *Arexvy*, which became the first RSV vaccine approved in 2023 and protects older adults, reached about US$734 million in sales in 2024, down 52% from the previous year, according to the company's year-end earnings report.

GSK placed some of the blame on the CDC after the agency's Advisory Committee on Immunization Practices changed its recommendations on who should get vaccinated against RSV last year, potentially reducing the patient population. Still, the pharma company was bullish on *Arexvy's* future, with revaccination and age cohort expansion expected down the road.

"We really are in the foothills of this vaccine," said Emma

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In Brief...

- **Sigma Healthcare** announced its merger with the **Chemist Warehouse Group (CW)**. This truly transformational merger brings together a leading Australian retail pharmacy franchisor and full-line pharmaceutical wholesaler and distributor with diversified and scaled operations and earnings base. The merger also combines Sigma's extensive state-of-the-art distribution infrastructure with Chemist Warehouse's leading retailing know-how. *Vikesh Ramsunder*, Sigma CEO and Managing Director said "Reaching this milestone today with the strong support we've received from shareholders – both new and long term – is incredibly humbling. It marks the pinnacle of a multi-year engagement process which wouldn't have been possible without the continued dedication and commitment of hard-working team members from both companies and support from our franchisees."
- **Eli Lilly** unveiled its highly ambitious plan to build four new production facilities in the U.S. at a cost of more than US$27 billion. This amounts doubles what was previously earmarked for domestic manufacturing since 2020, bringing the total outlay to more than US$50 billion. "This represents the largest pharmaceutical expansion investment in U.S. history," Lilly CEO *David Ricks*, said during a press event where he referred to the new facilities as "mega sites".
- The **U.S. Food and Drug Administration (FDA)** has approved GSK's *Penmenvy* vaccine for people ages 10 to 25 against meningococcal serogrouops A, B, D, W and Y (MenABCWY), which together cause the most invasive

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IFPW Conducts Member Visits in Saudi Arabia

IFPW has a deep commitment to its members and supports them in a variety of ways. We traditionally conduct networking meetings in the form of the annual CEO Roundtable for members and the biennual General Membership Meeting which was recently held in Miami, FL and will move to Mexico City in 2026. The IFPW Foundation provides leadership development opportunities for emerging executives in the form of onsite coaching assignments in the rapidly expanding STEP Leadership program.

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REGISTRATION IS OPEN
for the
2025 IFPW CEO Roundtable
Please check your email for your invitation to our members-only annual meeting at the Corinthia Hotel, London, U.K.
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Member Visits *(cont'd.)*...

When provided the opportunity IFPW will conduct on site member visits in order to learn more about market trends in regions of particular interest. Saudi Arabia is a country in transition with an emerging economy diversifying away from oil. George Bray, VP Member Engagement visited with both Salehiya Healthcare and Tamer Group in Riyadh, Saudi Arabia in early February 2025. Two of the top five pharmaceutical distributors in Saudi Arabia, Salehiya and Tamer are transforming their companies and preparing for the continued growth of the pharmaceutical industry. Family owned with an eye toward diversifying their services from traditional pharmaceutical distribution by exploring consulting, manufacturer services, and clinical trial services, both companies are working hard to develop more value-added services for the Saudi Ministry of Health, pharmacy and hospital customers, as well as manufacturers.

The world knows Saudi Arabia because of the country's geopolitical strength and the importance of oil in the world's economy. However, the transformation that is taking place in the Saudi economy is of great interest to IFPW members. Both Tamer and Salehiya are active members of IFPW and plan to attend the IFPW CEO Roundtable, in London in May. Please make plans to attend this member-only event May 7th and 8th at the Corinthia Hotel in London, UK.

If you would like to host IFPW at your company for an onsite visit please reach out to George Bray either by email at george.bray@ifpw.com or WhatsApp at +16143974615 or Chris Goetz at chris.goetz@ifpw.com or WhatsApp at +17039275186

Challenges Mount *(cont'd.)*...

Walmsley, CEO of GSK, during the fourth quarter earnings call.

In addition, *Arexvy* dominated the RSV space in 2024, holding onto about 58% of market share for the year, said Luke Miels, GSK's chief commercial officer.

GSK is aiming to hold onto its market control over Pfizer, which also saw sales of its RSV vaccine for older adults, *Abrysvo*, decline last year. In fact, *Abrysvo* sales plummeted 62% year over year in the fourth quarter alone. But Pfizer executives also noted during the company's year-end earnings call that the drug notched a 13% increase in market share during the year.

Moderna launched its RSV vaccine *mResvia* last year, marking the biopharma's second approved product. However, full-year sales were just US$25 million. The vaccine is the third RSV shot approved for older adults, and like Pfizer and GSK, the company is bullish on its prospects.

Now at the helm of HHS, Kennedy has wide-ranging ability to interfere with standardized vaccine polices, such as changing the role of ACIP, which advises the CDC on the use of vaccines.

Pfizer CEO Albert Bourla said he was "cautiously optimistic" about Kennedy's leadership position during the earnings call and noted he was looking forward to working on areas of agreement, such as chronic disease.

"The president introduced me to him [Kennedy], and we had dinner all three together, and we tried to understand his view," he said. "Do I expect that we will agree on everything on vaccines? I don't know. But I think probably … he will have a way more tempered view on how to interact with the vaccines. I think there are a lot of opportunities that probably outweigh the risks that we have with the radical change that… we are seeing now with the Trump administration."

Moderna CEO Stephane Bancel also offered some insight into how the company views the administration's new leadership during the year-end earnings call.

"We look forward to working with the new team as they get confirmed by the Senate," Bancel said. "Vaccines are a very important piece of keeping people healthy, and we look forward to having those discussions as people get confirmed."

Looking ahead, drugmakers are intent on expanding their RSV base and are still funneling R&D dollars into new vaccines.

Moderna is on the cusp of potentially snagging approvals for three new vaccines this year, including its next-gen COVID vaccine, an RSV jab for high-risk adults between 18-59 and a flu-COVID combo shot for people 50 and older.

With upcoming Prescription Drug User Fee Act (PDUFA) dates in May and June for the new COVID and RSV shots, the biopharma has a lot on the line over the next several months. Moderna is also in a pivotal phase 3 study for *acytomegalovirus* vaccine candidate and a two-season pivotal phase3 study for a norovirus vaccine.

Elsewhere, Sanofi reported it moved forward with six new vaccine studies during the fourth quarter of 2024, including a phase 3 study for a candidate in pneumococcal in children. And GSK noted its pipeline includes plans to expand its shingles vaccine label during the first half of 2025.

In Brief (cont.)

meningococcal disease (IMD) cases globally. With the approval, GSK adds a key new option to its market-leading meningitis vaccine portfolio. In a phase 3 study, GSK's vaccine, given in two doses six months apart, showed immunocological noninferiority to one dose of *Menveo*. In addition, the shot elicited noninferior immune response against 110 MenB strains compared to two doses of *Bexsero*.

- **Celltrion** (South Korea) is poised for a string of biosimilar submissions in Japan. The filing spree is driven not only by the firm's development efforts, but also by the Japanese government's policy change to waive submission of data in Japanese subjects in certain cases. If successful, the biosimilars under review or in the pre-filing stage are likely to receive approval sometime this year or next year. Despite domestic political turmoil as well as economic indicators such a low growth, a strong dollar versus the won and poor investment sentiment, the Korean biosimilar market has seen major strides, with national medicines market exceeding US$20.5 billion for the first time.
- The government of Vietnam wants to attract overseas investment to encourage domestic drug development, manufacturing, and commercialization through the latest amendment of its 2016 Law on Pharmacy, lifting part of the restrictions on foreign-invested enterprises (FIEs) and increasing their involvement in Vietnam. This will give FIEs more business opportunities to directly engage in the pharma business in Vietnam.

(Sources: Company Press Releases, Drug Store News, FiercePharma, PharmaTechnology, PharmaVoice and Scrip Citeline)