IFPW FOCUS
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IFPW to Launch ESG Framework to Serve as Standard for the Pharma Industry

On February 24th, The International Federation of Pharmaceutical Wholesalers (IFPW), in partnership with member companies (including global healthcare company AmerisourceBergen and IQVIA) will launch an ESG Framework to serve as a valuable resource for the industry. Leveraging insights from a wide range of healthcare organizations, the IFPW Framework for ESG is intended to create global alignment and consistency across the pharmaceutical sector regarding how to effectively communicate and report on the impact of environmental, social, and corporate governance initiatives to advance the supply chain forward.

A press release will be sent via Constant Contact to all IFPW member companies on Friday, February 24, 2023. Please circulate internally and on your social media outlets.

Biosimilars Present Significant U.S. Competition for the Blockbuster Humira

(Source: An article by Scott Gottlieb & Benedic N. Ippolito for the American Enterprise Institute)

Humira, the highest-selling medication in the world, is facing its first competition from *Amjevita*, a copycat biosimilar manufactured by Amgen. The entry of this first "generic" competitor brings to light biosimilars' ability to offer significant saving and price competition as well as increase patient access.

Unlike the blockbuster *Humira*, *Amjevita* was introduced to the U.S. market at two different prices – one with a price 5% lower its name brand predecessor and the another that is 55% lower. It is anticipated that the higher-priced version will be eligible for rebates which will result in lower prices for purchases. This is an arrangement now common among brand name prescription drugs and can benefit key market players such as Pharmacy Benefit Managers (PBMs) or insurers.

What makes *Amjevita* unique is the lower price point option, which is likely to come with little or no rebates resulting in very little gap between list and net prices.

The current pricing structure for brand name medications – with higher list prices and lower post-rebate prices – reflects current market incentives. For example, reimbursement of PBMs is frequently a function of the list price of medications. Insurers may also prefer this since it puts more of the financial costs to those taking the medications through coinsurance and placing less pressure of premiums. Incentives for this pricing structure option have been particularly strong in the U.S. Medicare Part D, where the program is thought to incentivize plans to prefer drugs with high prices and large discounts. All of this has encouraged drug makers to continue to maintain high list prices and large rebates/discounts, often at the expense of patients who pay out-of-pocket based on the higher list price.

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In Brief...

- **Biogen** CEO, *Chris Viehbacher*, announced that *Stelios Papadopoulos, Ph.D.*, will retire from Biogen's board of directors, potentially giving Viehbacher more freedom to make bold moves within the company. Viehbacher, who took over the role of CEO in November of 2022, has made transforming Biogen a top priority as the company attempts to recover revenue declines across its business sectors. Viebacher is looking to its Easai-partnered Alzheimer's drug *Leqembi* and Sage Therapeutics-shared depression med *zuranolone* to turn around the company's revenue challenges.
- **Johnson & Johnson's (J&J)** partnership with **Arrowhead Pharmaceuticals** has come to an end following the return of Arrowhead's *NASH program* which included the company's hepatitis work. J&J's **Janssen** business unit did not select any candidates beyond the *NASH* product stemming from a 2018 licensing collaboration. Without the *NASH* product, dissolution of the partnership was the only option. Separately, J&J announced the appointment of *John Reed, M.D., Ph.D.,* to the Company's executive committee as Executive Vice President of Pharmaceuticals. Reed previously served as Executive Vice President, Global Head of Research and Development for **Sanofi**.
- U.S. insurer and patient care provider **Kaiser Permanente** announced an operating loss of US$1.3 billion and a net loss of nearly US$4.5 billion for the year ended 2022. The losses are contributed to a US$4.2 billion increase in operating expenses, despite the US$2.3 billion increase in operating revenues. This is in contrast to its US$611 million operating income for 2021 and operating income of US$8.1 billion FY2021.
- *Bill Anderson*, former head of **Roche Holding AG's** pharmaceutical division will replace *Werner Baumann* as CEO of **Bayer AG**. Baumann's departure comes a year earlier

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Humira (cont.)

The U.S. Inflation Reduction Act is designed to level the playing field when it comes to the preference for high list prices in Medicare Part D. Also there appears to be greater recognition of the distortions caused by the high list prices in general.

Amjevita's two-tiered launch price adds additional pressure this fee arrangement, although it remains to be seen whether this is an one-off situation or a prediction of what is to come.

For now, the market potential for the low list price version will be constrained to the portion of the market that does not prioritize rebates. This will likely include integrated health systems such as Kaiser, which acts as both the provider and insurer. As was with the launch of the two-tiered pricing system for an insulin product, take up may be low in the commercial market and Medicare. Regardless, *Amjevita* will be an important test of the demand for this pricing model.

The availability of the two-tiered option exposes the magnitude of the rebates paid on drugs and could encourage other drug makers to launch drugs in a similar fashion.

The other noteworthy observation is the significant price reduction being offered by Amgen for *Amjevita*. While the lower priced version is expected to come with no additional rebates, it is 55% lower than the current list price of *Humira*. This is lower than the current net price of *Humira* post-rebates which is 40% lower than its list price. Exactly how much of the biosimilar will initially sell at this price is not yet clear. That will, in part, depend on factors such as *Humira's* use of multi-year contracts and whether *Humira's* net price is adjusted in response to the biosimilar.

Amjevita is the first of eight biosimilars that have been approved, with more launches expected during the summer of 2023. It is anticipated that prices will drop with subsequent entries, particularly since some will be deemed interchangeable. It is not likely that these biosimilar prices will be reduced as much as small molecule drugs. However, additional price reductions are expected as the market for *Humira* biosimilars becomes more competitive.

How Restructuring the FDA Could Affect the Pharma Industry

(Source: An article by Karissa Waddick for PharmaVoice)

It has long been a discussion among pharmaceutical industry officials that dividing the U.S. Food and Drug Administration (FDA) into two agencies – one that regulates medical products and one that regulates food – would improve efficiency. Recently the agency announced a proposal to restructure its *Human Foods Program*. While this is not as drastic, it could provide upsides for pharma.

The proposal was announced February 1st after the non-profit FDA oversight group, the Reagan-Udall Foundation (created by the U.S. Congress) recommended a number of structural changes to the food program in December amid controversy and criticism of the FDA's handling of the baby formula shortages. The group noted considerable concerns regarding the "lack of a single clearly identified person to lead the *Human Foods Program*," which it argued "has adversely impacted the organizational culture and led to overlapping roles and competing priorities that result in what is perceived as constant turmoil" at the agency.

Steve Grossman, executive director of the Alliance for a Stronger FDA and a former deputy assistant secretary of health at HHS said the FDA's food program has historically lacked clear lines of authority and is chiefly managed by the commissioner.

Under the FDA's proposal, a new deputy commissioner for human foods would be charged with overseeing all policy, strategy and regulatory activities related to food and nutrition. The agnecy's Office of Regulatory Affairs (ORA), which is responsible for inspection of all FDA-regulated products and manufacturers, would also be reconfigured and "transformed into an enterprise-wide organization.

If the agency's proposed revamp addresses consumer concerns and improves its ability to effectively regulate, that could have positive reputational impacts on its drug division as well.

Likewise, under the restructuring plan, the FDA also announced it would strengthen its "enterprise information technology and analytical capabilities," across the entire agency to "facilitate communication, more efficient operations and enhanced empirical risk algorithm."

These improvements, could have trickle effects on its drug and biologics divisions, potentially enhancing operational speeds for drug reviews.

A realignment of the ORA could also mean changes for how the FDA handles drug facility inspections, including state and local safety partnership functions.

Thus far, the FDA has revealed little about what the ORA restructuring might look like. As the agency looks for public comment on the proposal and releases finalized plans, pharma companies should stay tuned for details on how the newly-envisioned ORA might meet their specific needs and priorities.

In Brief (cont.)

than scheduled but was not a surprise given pressure by shareholders since the US$66 billion acquisition of Monsanto in 2018. Anderson will work alongside Baumann beginning in April until Baumann's departure date, which was not given.

- Sales of **Pfizer's** Covid-19 vaccine, *Comirnaty*, are expected to increase by 16% through 2023. *Comirnaty* is expected to maintain the sales dominance it had through the Covid-19 pandemic going into the future. *Comirnaty* is the leading prophylactic vaccine for Covid-19. In the long term, *Comirnaty* is expected to continue its momentum, with forecast sales up by more than 20% from 2024 to 2027.
- **Daewoong Pharmaceutical** has announced that it recently submitted a new drug application (NDA) for *Fexuclue*, a GERD drug, in Saudi Arabia. This is the 11th NDA submitted in 11 countries around the world one year after securing permission for *Fexuclue* in South Korea. The culumlative anti-ulcer drug, according to 2021 data from **IQVIA Global Midas** is estimated to be worth US$1.61 billion based on the 11 countries submitted for drug approvals. This includes Brazil, the Phillippines, Indonesia, Thailand, Mexico, Chile, Ecuador, Peru, Colombia, Vietnam and Saudi Arabia.

(Sources: Drug Store News, FiercePharma, Pharmaceutical Technology, Scrip Intelligence, and World Pharma News)