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The Biden Administration Eyes the Seizure of Drug Patents as a Tool to Lower Drug Prices

(Sources: An article by Fraiser Kansteiner for FiercePharma, and an article by Patrick Wingrove for Reuters)

The Biden administration has determined it has the power to take back patents of certain high-priced drugs, as first reported by the news agency Politico. "March-in" rights on government-funded research have long been debated as a potential measure to reduce drug prices, but never actually deployed.

Under the announced plan, the U.S. government would consider overriding the patent for high-priced drugs that have been developed with the help of U.S. taxpayer dollars and letting competitors manufacture them to drive down the cost.

Under the draft roadmap, the government will consider factors including whether only a narrow set of patients can afford the drug and whether drugmakers are exploiting a health or safety issue by hiking prices.

In a 15-second video released to YouTube, President Joe Biden promised the move would lower prices.

"Today, we're taking a very important step toward ending price-gouging so you don't have to pay more for the medicine you need," he said.

The move forms part of President Joe Biden's broader attempt to slash drug costs. Notably, the president's administration helped pass the Inflation Reduction Act (IRA) last summer, which introduced Medicare price negotiations that are not supported by the industry.

Outside of the IRA, the Federal Trade Commission has been taking actions to curb drug prices. For instance, the FTC recently released a policy statement warning brand-name drugmakers the agency could take legal action if patents are improperly listed in the FDA's Orange Book.

The industry has already responded sharply to the "march-in" talks. Wednesday afternoon, spokesperson Megan Van Etten for the trade group PhRMA suggested the move would constitute "yet another loss for American patients."

"The Administration is sending us back to a time when government research sat on a shelf, not benefitting anyone," she said in an emailed statement.

In a follow-up email, PhRMA argued the U.S. leads the world in drug development "precisely because" the embedded system allows the government, private sector and academic researchers to work together—a configuration that would be upended by the employment of march-in rights.

The march-in authority permits the government to grant patent licenses to other parties—or reclaim licenses for themselves—if taxpayer funding underpinned the patent owner's R&D process. The authority was carved out in the Bayh-Dole Act of 1980, and, in theory, it could help introduce competition and lower prices for consumers. But the rights have never been used

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In Brief...

- **Walgreens** announced the launch of *Rx Savings Finder*, a simple-to-use digital tool designed to assist customers in saving money on prescription medications. The tool finds free, third-party discount cards, providing patients with an easy way to find lower prices on their Walgreens medications. "Inflation not only impacts our pockets but can have serious implications on health," said *Rick Gates*, Walgreens Chief Pharmacy Officer. "Over one-third of Americans have avoided a prescription refill to reduce costs…and this is very concerning."
- **Johnson & Johnson** outlined plans to develop two novel oral drugs in immunology, a first-in-class oral peptide targeting IL-23, *JNJ-2113*, and an oral small-molecule IL-17 inhibitor, *JNJ-1459*, during an investor call earlier in December. With a long and strong history of immunology drugs such as *Remicade, Stelara*, and *Tremfya*, Johnson & Johnson is looking to continue its leadership in categories like psoriatic arthritis and inflammatory bowel disease with the development of new oral medicines.
- **Cigna** reportedly ended its efforts to negotiate an acquisition of rival **Humana**, according to a report by Reuters. Reuters noted that the two companies failed to agree on price. Additionally, the report said the company announced plans to buy back US$10 billion worth of shares. The acquisition of Humana by Cigna would have created a company with a value exceeding US$140 billion, based on their market values but was certain to come under antitrust scrutiny.
- Pharma manufacturer **AbbVie** will acquire **ImmunoGen** for US$10.1 billion in cash. ImmunoGen is the maker of the ovarian cancer treatment *Elahere*, which won approval by the U.S. Food and Drug Administration approximately one year ago. The acquisition accelerates AbbVie's entry into the solid

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Pharmaceutical Industry Groups Release Statement at COP28

(Source: An article by Jenna Philpott for Pharmaceutical Technology)

Several pharmaceutical industry advocacy and lobby organizations have joined together to release a joint industry statement supporting the Declaration on Climate and Health released at the COP28 meeting in Dubai (an international gathering of national leaders, regulators, and environmental scientists) and is centered on efforts to set and meet climate-related targets.

The joint statement is from associations in Europe, the U.S., Canada, and Japan, including the Association of the British Pharmaceutical Industry (ABPI), European Federation of Pharmaceutical Industries and Associations (EFPIA), Pharmaceutical Research and Manufacturers of America (PhRMA), as well as The International Federation of

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Biden Administration (cont.)...

in practice.

This week's developments come after the National Institutes of Health in March rejected a petition to leverage the authority around Pfizer and Astellas' pricey prostate cancer therapy Xtandi. The same fate befell a similar petition back in 2016.

In its rejection, the NIH said it shared petitioners' concerns about high drug prices, but that it had also determined Xtandi was "widely available to the public on the market."

Further, given the drug's remaining patent life and "lengthy administrative process involved for a march-in proceeding," NIH figured the march-in authority wouldn't be an effective means of lowering Xtandi's price.

COP28 (cont.)...

Pharmaceutical Manufacturers and Associations (IFPMA) which represents more than 90 pharmaceutical companies worldwide.

The declaration highlights the negative impacts of climate change on health, and details objectives to ensure better health outcomes, such as implementing adaptation interventions against climate-sensitive disease and health risks. The aim of the declaration is to strengthen the implementation of policies to protect populations most vulnerable to the health impact of climate change.

In the statement, the industry organizations highlighted that pharmaceutical companies are becoming global leaders when it comes to reducing carbon emissions, acting as part of global initiatives, and setting net-zero and carbon-neutrality targets. Many pharmaceutical companies have made net zero commitments, with some committing to become completely net zero by 2045. Among other announced initiatives, companies like GSK are starting an R&D program to find an alternative, greener propellant for their rescue inhalers, with 55% of GSK's total climate impact coming from patient use of these inhalers. If successful, the project could reduce the environmental impact of rescue inhalers by 90%.

Pfizer has set a goal to decrease its greenhouse gas (GHG) emissions by 95%, and value chain emissions by 90%, from 2019 levels, by 2040. The company plans to do this with renewable energy investments, aiding suppliers to set science-based emission reduction goals, and reducing emissions related to upstream logistics and business travel.

However, companies also need to focus on initiatives to reduce Scope 3 emissions, which is where most emissions lie. This is a shared responsibility between pharmaceutical companies and the supply chain, but essential if companies are going to meet net zero targets.

December 3, 2023 was also recognized as the first ever Health Day, and to mark the occasion, the U.S. Department of Health and Human Services (HHS) released a climate change and health equity strategy supplement, summarizing the work of agencies across the HHS to support efforts to curb climate change in the U.S. health sector. The supplement lays out over 50 planned actions, including an update on its collaboration with the NHS in England to align suppliers' procurement requirements, including target setting and emissions disclosures.

The declaration and associated statements come after COP28 President Sultan Al Jaber claimed there is "no science" indicating that a phase-out of fossil fuels is needed to restrict global heating to 1.5C during a live online event on November 21st. The president has since insisted that he respects the science, saying "We are here because we very much believe and respect the science. Forty-three percent of global emissions must be reduced by 2030," at a press conference held on December 4th at COP28.

Both HHS and NHS also emphasized the importance of the World Health Organization (WHO) Alliance for Transformative Action on Climate and Health (ATACH) platform to galvanize resources, knowledge, and expertise in the statement. The alliance was introduced at COP26, to help countries deliver commitments to build climate resilient and low carbon sustainable health systems.

In Brief (cont.)

tumor space and strengthens the company's oncology pipeline, according to AbbVie CEO, *Rick Gonzalez*.

- Swiss pharma manufacturer **Roche** is acquiring **Carmot Therapeutics** for US$2.7 billion. The buyout centers around Carmot's pipeline of three GLP-1 agonists for obesity and related comorbidities, the most advanced of which is *CT-388*, a Phase II-ready once-weekly injectable for obese patients with or without type 2 diabetes, which has shown promise in an early clinical study. The other candidates are GLP-1 *CT-996*, a once-daily small molecule in Phase I in the same indication; and Phase II once-daily injectable *CT-868* (GLP-1/GIP) in obese patients with type 1 diabetes.
- **CVS Health** has introduced a new pharmacy reimbursement model, and brand for its health services segment that showcases continued growth opportunities for its businesses. The company also announced *CostVantage*, a new approach that evolves the traditional pharmacy reimbursement model and brings greater transparency and simplicity to the system. CostVantage will define the drug cost and related reimbursement with contracted pharmacy benefit managers and payors, using a transparent formula built on the cost of the drug, a set markup and a fee that reflects the care and value of the pharmacy services.
- New benchmarking data released by the **HDA Research Foundation** shows the continued value of specialty distributors in the U.S healthcare ecosystem. The HDA Foundation's latest *"94th Edition HDA Factbook: The Facts, Figures and Trends in Healthcare"* quantifies the many way specialty distributors serve as vital partners within an evolving healthcare ecosystem," said *Perry Fri*, Executive Vice President for Industry Relations, Membership and Education of **HDA**, and COO of the HDA Research Foundation. "The industry does this by achieving impressive service levels and efficient delivery, ultimately ensuring providers have the necessary medicines and support to keep their patients healthy." The publication is available for complimentary download at ***https://www.hda.org/publications/94th-edition-hda-factbook-the-facts,-figures-and-trends-in-healthcare/.***

(Sources: Company Press Releases, Drug Store News, FiercePharma, Scrip Intelligence, Scrip Citeline and World Pharma News)