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## HHS Intensifies Pressure On Pharma With Most Favored Nation Pricing Benchmark

*(Source: An article by Jessica Merrill for Scrip Citeline)*

The Trump Administration is pushing ahead with plans to force lower drug prices in the US by requiring drug manufacturers to drop the price of drugs to the lowest available price in other countries that are part of the Organization for Economic Cooperation and Development (OECD).

The US Department of Health and Human Services (HHS) updated drug companies on the metric it intends to use to execute President Trump's executive order on May 20th, though like the original executive order, details remain scarce.

The Most Favored Nation (MFN) target price is the lowest price in an OECD country with a GDP per capita of at least 60% of the US's, HHS said.

"HHS expects each manufacturer to commit to aligning US pricing for all brand products across all markets that do not currently have generic or biosimilar competition with the lowest price of a set of economic peer countries," the agency stated.

The annual US GDP was US$82,769 per capita in 2023, according to the World Bank. US drug prices under the proposed plan, if aligned to this benchmark, would be tied to the lowest price across Australia, Austria, Belgium, Canada, Czech Republic, Denmark, Finland, France, Germany, Iceland, Ireland, Israel, Italy, Japan, Korea, Lithuania, Luxembourg, the Netherlands, New Zealand, Norway, Slovenia, Spain, Sweden, Switzerland, and the UK.

There were no additional details provided about how the administration would force price concessions in the private commercial market when contracts are in place with payers or how drug manufacturers could maintain near- and long-term financial forecasts with such a high level of disruption in the US market.

There is no clarity in general on how the Trump administration could enforce the demand, which appears voluntary – at least initially.

Given that the executive order doesn't require legislative action by Congress or changes to the Medicare drug price negotiation program, many industry observers and investors saw the original announcement as more bluster than action. The EO stated the administration will take additional action if drugmakers don't comply with the request, suggesting reimportation of more affordable drugs on a case-by-case basis or proposed rulemaking.

Slashing US drug prices so drastically and quickly would be devastating to the industry, pharma company leaders have warned.

"Our take is that the administration's demand is extreme and we do not think that the industry can deliver what is stated," Leerink analyst David Risinger said in a same day note.

Industry leaders attending the Bank of America Global Healthcare Conference May 13th & 14th were pressed for early

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## In Brief...

- **Cardinal Health** reported third quarter fiscal year 2025 revenues of US$54 billion, in line with third quarter results in 2024. Third quarter revenue increased 19% excluding the impact of a previously communicated customer contract expiration. Third quarter GAAP operating earnings increased to US$730 million. "Our strong momentum continued into our third quarter as our team's ongoing focus on operational execution and value creation led to excellent financial results," said Jason Hollar, the company's CEO.
- **MSD** president, *Kyle Tattle*, criticized what the company saw as a U-turn in drug pricing policy in Japan since late last year, which significantly and negatively impacted several of its products in 2025 with earlier-than-anticipated price cuts. He warned that if such uncertainty continues, it will ultimately drive investments away from Japan and worsen drug lags and losses in the country. In the FY2025 drug price revision announced in April, Japan for the first time in an "off" year implemented a price maintenance premium (PMP) return, or a one-time payback of previously granted PMPs after generic/biosimilar entries, or 15 years of listing. This included two MSD products, *Januvia* and *Bridion*.
- **Pfizer** announced it has entered into an exclusive global (exclusive of China) licensing agreement with **3SBio Inc.,** a leading Chinese biopharma company, for the development, manufacturing and commercialization of *SSGJ-707*, a biospecific antibody targeting PD-1 and VEGF, and currently undergoing several clinical trials in China for non-small cell lung cancer. Under the agreement, 3SBio and its subsidiaries **Shenyang Sunshine Pharmaceutical Co., Ltd.** and **3SBuojian**

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## Generative AI on Track to Shape the Future of Drug Design

*(Source: An article by Nat Mach for World Pharma News)*

Using advanced artificial intelligence, researchers have developed a novel method to make drug development faster and more efficient. In a new paper, Xia Ning, lead author of the study and a professor of biomedical informatics and computer science and engineering at the Ohio State University, introduced DiffSMol, a generative AI model capable of generating realistic 3D structures of small molecules that can serve as promising drug candidates.

DiffSMol works by analyzing the shapes of known ligands – molecules that bind to protein targets – and using these shapes as conditions to generate novel 3D molecules that better bind to the protein targets. Study results showed that when used to create molecules with the potential to quicken the drug-making process, DiffSMol, as a 61.4% success rate, outperforming prior research attempts that achieved success about 12% of the time.

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## HHS Intensifies *(cont'd.)*...

reaction to President Donald Trump's executive order on US drug pricing, but with the conference kicking off just one day after the president's announcement, executives are still struggling to understand what the new policies could mean for their companies' top and bottom lines.

It's difficult to quantify the delta between US drug prices and those in other nations because drug price negotiations are usually confidential, both with US payers and with government payers outside the US. Even when list prices are available, drug manufacturers frequently offer steep rebates in the US to negotiate formulary access, sometimes offsetting list prices by as much as half, and often offer discounts in other countries as well.

Still, the price differences can be dramatic. As an example, the US list price for AbbVie's *Skyrizi (risankizumab)*, a high-growth drug for plaque psoriasis is US$22,383.49 for one dose, according to AbbVie's website, while in the UK the list price is £3,326.09 (currently US$4,452.54) under the government's National Institute for Health and Care Excellence (NICE) assessment, though it is made available at a further discount.

Merck & Co. US Human Health president Jannie Oosthuizen discussed the difference between pricing in the US and Europe during a discussion at the Bank of America healthcare conference, pointing out that the difference varies depending on the lifecycle of a drug.

"We usually start much, much closer, and then in the United States, we have an ability to increase price," he said. "But in the rest of the world, it's pretty much no price increase and more often continuous price decreases, right? So, you have a divergence that really gets increasingly bad overtime."

## Generative AI *(cont'd.)*...

"By using well-known shapes as a condition, we can train our model to generate novel molecules with similar shapes that don't exist in previous chemical databases," said Ning.

Once DiffSMol learns the shapes of these ligands, the team's model can also tailor those new molecules to encourage certain binding characteristics. According to the paper, this suggests the model could modify them to have more favorable drug-like properties, altering aspects like their synthesizability or toxicity.

It takes about a decade for a drug to be developed and brought to market but shortening that time could open up new paths to develop novel pharmaceuticals and agrochemical agents for use in many different industries. Chiefly, compared to existing computational methods used to design drugs, DiffSMol takes only one second to generate a single molecule, said Ziqi Chen, co-author of the study and a former doctoral student in computer science and engineering at Ohio State.

"Generative AI models have the potential to substantially expedite this process and im prove cost efficiency," Chen noted.

To demonstrate DiffSMol's abilities, researchers conducted case studies on molecules used in two crucial drug targets, one called *cyclin-dependent kinase 6 (CDK6)*, which can regulate cell cycles and disrupt cancer growth, and neprilysin (NEP), which is used in therapies aimed at slowing the progression of Alzheimer's. Their results revealed that the molecules DiffSMol created would likely be very effective, according to Ning.

"It's very encouraging for us to find molecules with even better properties than known ligands," she said. "It indicates that our developed models have great potential in identifying good drug candidates."

The researchers also made DiffSMol's code available for other scientists to access and use.

Currently, DiffSMol is still only able to generate new molecules based on shapes of previously known ligands, which is a limitation the team hopes to overcome in future work.

Further research will also be aimed at improving the model's ability to learn from complex molecule data and generate molecules that exhibit a wider range of potential interactions.

Despite the need for more testing, the team anticipates that continued progress in AI will one date allow their work to reach new levels of success, partly due to AI's global rise in popularity.

## In Brief (cont.)

**Pharmaceutical (Shangahi) Co., Ltd.** will grant Pfizer an exclusive global license to develop, manufacture and commercialize SSGJ-707 worldwide with the exception of China. The deal involves an upfront payment of US$1.25 billion, and additionally US$4.8 billion in milestone payments.

- NY-based drug maker **Regeneron** announced that it would acquire **23andMe's Personal Genomics Service, Total Health and Research Services** business lines, along with its **Biobank** and associated assets for US$256 million. The purchase does not include **Lemonaid Health** business. Regeneron said the deal will allow 23andMe to continue its consumer genome services uninterrupted, with the genomics firm becoming a wholly owned subsidiary of Regeneron. Additional details will be forthcoming; however the company did say that the deal is complementary to the work of the Regeneron Genetics Center, whose research includes nearly five million participants from around the world.
- **Rite Aid** announced that it has successfully entered into a series of sale agreements and pharmacy services transaction agreements. Included is the rolling transition of pharmacy assets from more than 1,000 store locations across the U.S. to operators including **CVS Pharmacy, Walgreens** and others. During the transition, Rite Aid said the stores will remain open, and customers can continue to access their pharmacy services, including prescription refills and immunizations, without interruption.
- **Sanofi** is acquiring **Vigil Neuroscience** for US$8 per share in cash, representing an equity value of US$470 million, plus a non-transferrable contingent value right of US$2 per share, conditional upon the first commercial sale of *VG-3927*, an Alzheimer's drug. Vigil reported positive Phase I data on the oral small molecule *TREM2* agonist in January and was looking to advance a once-daily 25mg dose into Phase II in the third quarter of this year.
- **U.S. Food and Drug Administration (FDA)** biosimilar approvals reached a record of 19 in 2024, with projections indicating that 2025 could surpass that milestone. In addition to the increase in biosimilar approvals, there is a growing trend emphasizing the importance of strong relationships in clinical supply chains, major pharma companies' intentions to establish manufacturing facilities in the U.S. and potential effects on pharma investment and tariff concerns in the U.S.

*(Sources: Drug Store News, FierceBiotech, FiercePharma, Scrip Citeline and World Pharma News)*