CAPITOL STREET

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March-in Rights Guidance Released

Biopharma Widespread Use & Singling Out Not Expected

Relevant Companies: Biopharmaceuticals

Our Take & Next Up

Today, the Department of Commerce (DOC) released guidance on how the agencies should review when determining exercising march-in rights for certain therapies (here). NIST will convene a webinar on December 13 to discuss the guidance, according to the 37-page notice posted on the Federal Register. The march-in rules are not healthcare specific, and impact all forms of technology, with biotech and other technologies referenced (e.g., water filtration, 3-D printing). This policy will take time to unfold, as rulemaking ensues (likely 1H 2024, as this is a request for information) after comments are accepted. The White House is likely using this is an election campaign talking point and noted (here) it does not plan to single out individual drugs/manufacturers OR endorse widespread use.

Key Points

The NIST guidance (here) does not endorse widespread march-in rights use. It notes the price and availability of that product to the public are among the factors the department will recommend that agencies consider in reviews. The administration states it is not endorsing widespread use of the authority and the HHS is not expected take action against any individual drugs for now.

PhRMA and individual manufacturers will likely flex their legal muscles on this one. The department will seek public feedback on the framework, which is likely to face sharp opposition from PhRMA, biopharmaceutical companies that argue it's illegal for the government to seize its patents and would disincentivize the development of new drugs. The proposal starts a stakeholder feedback period, with final rules in 2024 (election year). Lawsuits are likely to ensue if finalized.

Key to the guidance is the inclusion of price and availability as a criterion for march-in. The guidance is a result of a 9-month review by HHS and the Department of Commerce that has ended with the Biden administration determining that the agencies have the authority to invoke march-in rights and can include price and availability as factors for march-in consideration.

- As a reminder, one of the statutory criteria for march-in is if a patent holder has not taken within a reasonable time, effective steps to achieve practical application of a product in its field of use.
- In March, NIH previously declined to use the pricing as an availability factor when it reviewed a petition to exercise march-in rights for Xtandi (here). NIH, as a result, declined to exercise march-in because Xtandi was found "to be widely available to the public".

Newly confirmed NIH Director, Dr. Monica Bertagnolli, remarked during Senate confirmation she will use march-in rights in limited circumstances that "allows it to achieve its specific aim." To date, no agency has exercised its right to march-in. Even with the administration's support, Bertagnolli is expected to be careful in utilizing March-in rights. Xtandi's petition decline was also due to the remaining patent life and the lengthy administrative process for march-in. There will be other factors at play for the NIH to consider and we expect the agency to be very specific when considering pricing as a factor for future review.

It remains unclear which therapeutics could be folded in ~ Rare disease (mAb), Alzheimer's & autoimmune scenarios provided (~page 30) -- with manufacturing constraints (not pricing). The administration has said that the guidance does not target specific drugs and the potential usage scenarios laid out in the guidance do not include scenarios where drug pricing comes into play. Rare disease, autoimmune treatments, and Alzheimer's therapies are included in the agency's example scenarios for march-in review, but these would largely be triggered by manufacturing delays, not pricing.

The announcement presents another headline & perceived headwind for biopharma innovation. Biopharma already faces a difficult pricing environment with both federal pressures from drug negotiations and state pressure from drug affordability boards. The difficult financing environment also presents a challenge for small to mid-sized biotech manufacturers.

- **As a reminder, CMS is in the process of determining an initial price for each negotiation selected drug for 2026**. They are expected to offer an initial price by February 1 to each manufacturer with a justification. CMS has until September 1 to release the final maximum fair price, and until March 1, 2025, for the price explanation. The framework used will determine how the agency weighs negotiation factors and the information provided by drug manufacturers.
- **Colorado's Prescription Drug Affordability Boards (PDAB) is conducting affordability reviews for their 5 selected drugs (Genvoya, Enbrel, Trikafta, Stelara and Cosentyx).** The Board is starting with Trikafta with an affordability vote this month. CO PDAB has the authority to set an upper payment limit (UPL) which sets the maximum that a drug can be reimbursed for in the state. If the Board (1) determines a drug is unaffordable and (2) determines that an UPL is necessary, the board would undergo rulemaking in 2024.

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