

CAPITOL STREET

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PRV Passes House and Heads to Senate

BIOSECURE Expected in NDAA As Soon As This Week

Relevant Companies



»» Our Take & Next Up

While the House unanimously passed PRV late last night, its outlook in the Senate is murky, but definitely doable. On Dec. 1, the House unanimously passed legislation to extend the FDA's Pediatric Rare Disease Priority Review Voucher (PRV) program through FY2029 ([here](#)). The bill now moves to the Senate where it could see inclusion in a broader healthcare package (EPTCs, PBM reform, health extenders) in late December/January, despite objections from both progressive Democrats (e.g., Sens. Sanders, I-VT and Warren, D-MA) and Sen. Rand Paul (R-KY). As a reminder, Sen. Sanders has previously criticized the PRV program due to the ability to buy and sell the vouchers.

Meanwhile, BIOSECURE is moving and will likely be included in the final text of the reconciled *National Defense Authorization Act (NDAA)*, expected Thursday ([here](#)). Recall, the Senate-passed NDAA included a watered-down version of BIOSECURE, which we believe has a 70%+ chance of passage by year end. The provision bars federal agencies from contracting with Chinese biotech companies of concern, but no longer names certain entities like WuXi (our take [here](#)).

»» Key Points

The PRV program expired in part in December 2024, so extending the program is a positive for biopharma. As a reminder, the PRV program must be legislatively reauthorized before full expiration in September 2026. *The Mikaela Naylor Give Kids a Chance Act (H.R. 1262)* reauthorizes the FDA's Pediatric Rare Disease Priority Review Voucher (PRV) program through Sept. 30, 2029. This would be a little over 4-year reauthorization of priority review vouchers. The bill also expands FDA's authority to require pediatric cancer studies - including for combination therapies - and strengthen enforcement of study deadlines.

The Senate path to passage remains unclear, but inclusion in a December/January healthcare package is on the table. We could see the bill attempt to be hotlined, i.e. the measure will be called up to pass without a vote (by Unanimous Consent) with permission from leadership and Senate cmte Chairs. Or we could see the bill fall into a broader December/January healthcare package if progressive Senators like Sanders (I-VT) and Warren (D-MA) continue to object to the reauthorization.

All the oxygen in 2025 has been focused on the FDA Commissioner's National Priority Voucher (CNPV) program. The program has announced 15 CNPV recipients including Orforglipron (LLY) and Wegovy (NVO) for obesity and related health conditions. As a reminder, the CNPV program is designed to accelerate product reviews for key national priorities including public health, drug pricing, and domestic drug manufacturing. See our past analysis [here](#). Full list of CNPV candidates [here](#) and [here](#).

We have said the less onerous *BIOSECURE* language has a 70%+ chance of passage by year-end (our take [here](#)). The watered-down language includes companies named in the DoD [1260H list](#), a 5 year grandfather period, and protection from public release for new companies until a final determination. BGI/MGI is expected to be impacted due to their status on the 1260H list, while WuXi entities are not named at this time.

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