Evaluate Vantage

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US drug pricing reform happens at last

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As a host of industry-hated proposals look like becoming law in the US, Evaluate Vantage explains what might be coming.

The threat of pricing curbs in the world's most lucrative drugs market has long loomed over biopharma, but years of political inaction prompted many to shrug off the latest Democrat-led efforts as also likely to fail. Now a ruling over the weekend means that change is almost certainly on the way.

Drug lobby groups are already up in arms – a statement from Phrma said the bill would "threaten patient access and future innovations". But the proposals are likely to prove popular among a population widely concerned about the affordability of medicines.

The most seismic shift ahead sees Medicare being allowed to negotiate drug prices for the first time. *Evaluate Vantage* takes a look at the changes on the table.

What happened?

The Democrats' $750bn Inflation Reduction Act, a wide bill covering tax, climate and healthcare issues, was passed by the Senate over the weekend. The bill now moves to the House, which is also controlled by the Democrats, meaning that President Biden is likely to sign it into law in the coming weeks.

What proposals affect biopharma?

The most monumental proposal will allow Medicare, the government-funded healthcare programme for the over 65s, to negotiate drug prices directly for the first time. The scope is fairly limited, however, starting with 10 drugs from 2026, rising to 60 drugs by 2029. Some reports put the number at 20 by 2029, but the cumulative interpretation of the wording of the law seems to be the consensus for now.

The proposals apply to drugs covered under Medicare Part D initially, extending to Part B from 2028. Drugs covered by Part D are mostly small-molecule pills dispensed at pharmacies, but some self-injected biologicals are also covered; Part B includes a wider range of biologicals.

To qualify for negotiation a drug must be supplied by only one manufacturer (single source) and have been on the market for 9+ years for small molecules and 13+ years for biologics. Drugs also should have no generic or biosimilar equivalents. Other exemptions, for example around orphan exclusivity, apply.

A second reform is more punitive: manufacturers that hike the price of a prescription drug (covered by Medicare Part B and D) faster than inflation will have to pay a rebate. The original proposal saw the inflation

rebate also applied to the commercial market; that was not expected to pass, but the block still represents a major win for industry.

Separate proposals include: capping out-of-pocket Medicare costs at $2,000 a year; eliminating cost sharing for adult vaccines; and expanding eligibility for full Medicare Part D benefits under the low-income programme.

Another proposal that did not make it through was a $35-per-month cap on out-of-pocket insulin prices. Insulin pricing has been a huge topic in the US, however, and Bloomberg reported that Democrats might leave the full insulin cap in the bill and challenge the Republicans to vote to remove it. With November elections looming, such a move by the Republicans would not be a great look.

What has been the response?

SVB Securities wrote yesterday that “price control reality" had set in, and said the investment community had to reduce long-term sales estimates to reflect earlier declines in Medicare revenue. Lower return on investments must also be expected, they cautioned.

Industry could find ways to mitigate these changes, for instance by launching a product at a higher list price or authorising limited competition, which would render a product multi-source and ineligible for negotiation.

However, SVB voiced the widely held industry concern that the latest development would open the flood gates to further reform. Lawmakers will also try to limit manufacturers' ability to game the system in the future, they believe.

A lot to lose? Expensive Part D drugs					
Product	**Company**	**Possible year 1 negotiation**	**Estimated US LOE**	**Revenue tail lost**	**2026 US sales**
Eliquis	Bristol Myers Squibb	2026	2028	2 years	$9.2bn
Biktarvy	Gilead	2027	2033	6 years	$9.6bn
Tagrisso	Astrazeneca	2026	2032	6 years*	$4.4bn
Ozempic	Novo Nordisk	2026	2032	6 years	$6.8bn
Imbruvica	Abbvie	2026	2032	6 years	$3.3bn
**Has orphan status so might be exempt. LOE=loss of exclusivity. Source: SVB Securities.*					

William Blair analysts, meanwhile, pointed out that companies heavily reliant on Part D type medicines would feel the most pain. They singled out Bristol Myers Squibb, largely thanks to Eliquis and Revlimid, and said the bill could hit this company’s decision to invest in the Eliquis follow-on milvexian.

Large indications that typically afflict the elderly could now become less attractive for investment, they added.

For now, however, it is pretty hard to estimate the real impacts of this bill. For one thing, Medicare negotiators will chose the most costly 10 drugs at the time, and that remains some years away.

Investors largely shrugged off the news: the S&P Pharmaceutical Index was higher in early trade, with most big pharma stocks either flat or slightly higher. Some form of price control or other reform of the US healthcare system was going to happen sooner or later, and in reality biopharma is profitable enough to swallow these changes.

Affordability activists will be hope that this is only the beginning, of course. Whether that is the case will depend on the Democrats holding on to their slim majority in November and beyond.

Under threat? Medicare's big drugs in 2020					
Part D			**Part B**		
Product	**Company**	**Spend**	**Product**	**Company**	**Spend**
Eliquis	Bristol Myers Squibb	$10bn	Keytruda	Merck & Co	$3.5bn
Revlimid	Bristol Myers Squibb	$5.5bn	Eylea	Regeneron/Bayer	$3.0bn
Xarelto	J&J	$4.7bn	Prolia	Amgen	$1.6bn
Januvia	Merck & Co	$3.9bn	Opdivo	Bristol Myers	$1.9bn
Trulicity	Lilly	$3.3bn	Rituxan	Roche	$1.3bn
Source: CMS.					