

## Life Sciences &amp; Diagnostic Tools

## Takeaways from US election call: NIH flattish in FY24, FY25 less certain

Industry Overview

## How could the 2024 US election impact Tools &amp; Dx?

Earlier today, the BofA Healthcare Team hosted a conference call with Andy Bressler, BofA Health Care Policy Analyst, and Annie Palisi, BofA Macro Political lobbyist, to discuss the 2024 US elections and how the results could affect the US healthcare. Topics discussed of importance to our coverage include the outlook for NIH funding and the status of diagnostics industry legislation. Here are our takeaways.

## NIH budget likely flattish-to-slightly-up in FY24

On 1/7, Congressional leaders made a top-line FY24 budget deal, averting a 1/20 government shutdown. The deal included close to flat overall non-defense discretionary spending. Given this set up, our speakers see NIH funding as flat-to-slightly up yoy in FY24, in-line with our expectations ([see our 6/13/23 note for details](#)). However, while the likelihood is low, the speakers noted some risk of a budget cut. Specifically, the Fiscal Responsibility Act of June 2023 capped spending for appropriations bills that were not signed into law by 1/1/24. If these appropriations bills are still outstanding by 4/30/24, then the Federal Budget would be subject to a ~1% across the board cut.

## Flat NIH funding in FY25 under current assumption

For FY25, our speakers think that the NIH budget could be flattish yoy given that the agency still has bipartisan support despite a number of Republican NIH advocates having left Congress since 2016. However, if the Republican party sweeps the upcoming election cycle, then there could be more of a focus on cutting non-defense discretionary spending.

## LDT regulation progressing

After the FDA released a proposal to formally exert its authority to regulate Laboratory Developed Tests (LDTs; [see our 10/02/23 note for details](#)), there has been much debate on what it means for the diagnostics sector. For example, ACLA (American Clinical laboratory Association) called the proposal a burden on innovation, while AdvaMedDx (part of the Advanced Medical Technology Association) supports FDA's authority to regulate LDTs as it puts LDT providers on a more even playing field with IVD (in vitro diagnostic) device makers. With the public comment period now over, the speakers believe that the FDA will look to finalize the regulation in spring 2024 ahead of the election.

## PAMA, SALSA discussions to continue in 2024

On Medicare clinical laboratory payment rates, PAMA cuts that were to take effect in 2024 were once again delayed for another year. The lab industry is lobbying to enact legislation (e.g., SALSA) to offset or modify PAMA, but it remains to be seen how far such legislation will progress in an election year. As a reminder, until new legislation is enacted, clinical lab companies (e.g., Quest Diagnostics (DGX) and LabCorp (LH)) continue to assume in their guidance that PAMA cuts will resume in 2025.

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ACLA: American Clinical Laboratory Association

Dx: diagnostics

FDA: Food and Drug Administration

IVD: in vitro diagnostic

LDT: laboratory developed test

LST: Life Sciences Tools

NIH: National Institutes of Health

PAMA: Protecting Access to Medicare Act

SALSA: Saving Access to Laboratory Services Act

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