VALID act update

PIcc meeting 3/29/2023 – J. Lennerz

Update 3/29/2023

- **The VALID Act** is set to be reintroduced today — but its future is murky*

- VALID was cut twice from legislative packages
- VALID's main Senate champion retired

- **Rep. Larry Bucshon** plans to reintroduce the bill Wednesday afternoon with **Rep. Diana DeGette**

FACTS (summary)

- This year's bill will resemble the version that came from Senate HELP last year, **with some changes based on omnibus discussions**, according to a source close to the matter
- The bill will **not include a carve-out** for academic medical centers.

VALID: An oversight framework

- The bill would allow approval of one representative test.
- The LDT overhaul is needed to help developers react more quickly
- After VALID was cut from the FDA user fee reauthorization bill, advocates pushed to include it in the December omnibus.
- The provision didn’t make the final version, in part because academic medical centers said it would hamper their ability to deliver and develop new tests.

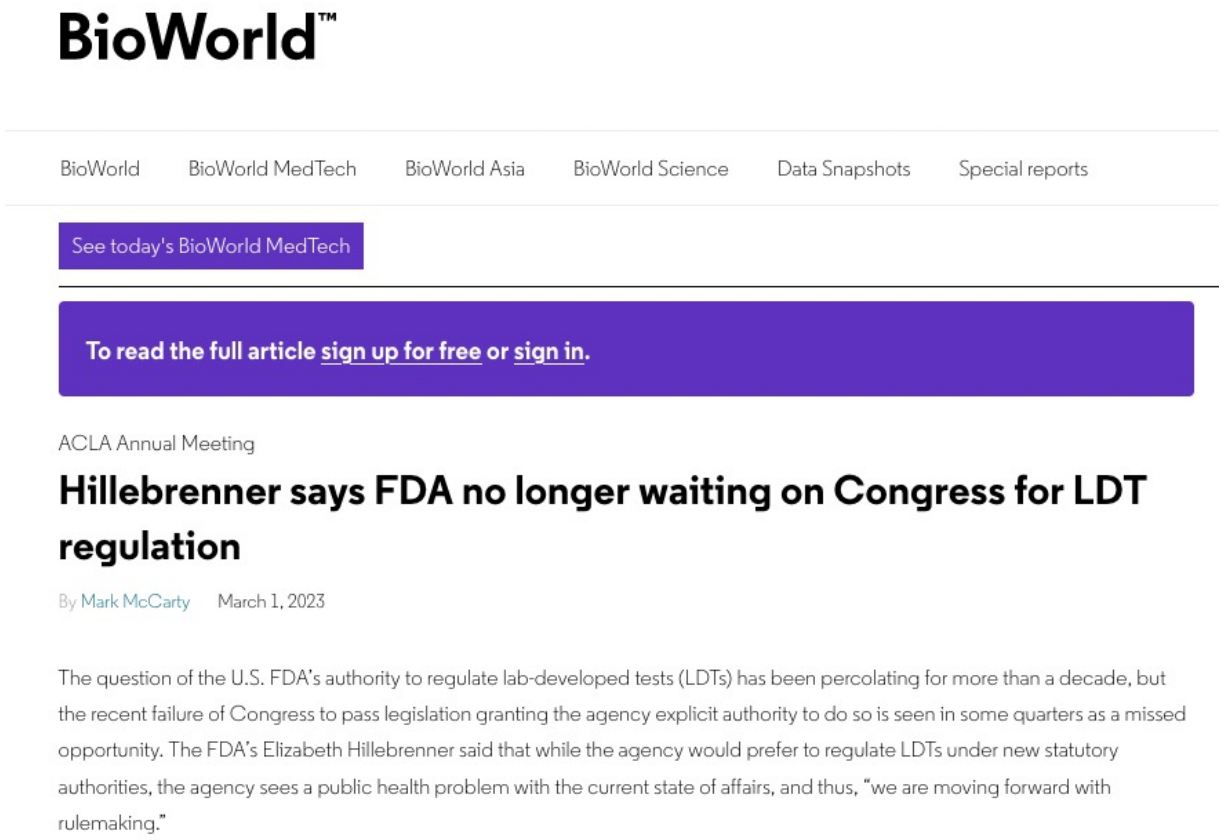
AMC (AAMC)

- Academic medical centers are still willing to **work on a policy agreement** — and having more time to do that is a benefit, said Heather Pierce, senior director for science policy and regulatory counsel at the Association of American Medical Colleges.

What if, what if not

- The agency is moving forward with **rulemaking** on diagnostic testing regulation

- The VALID Act is one of the **agency's top legislative priorities** for PAHPA reauthorization



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ACLA Annual Meeting

Hillebrenner says FDA no longer waiting on Congress for LDT regulation

By Mark McCarty March 1, 2023

The question of the U.S. FDA's authority to regulate lab-developed tests (LDTs) has been percolating for more than a decade, but the recent failure of Congress to pass legislation granting the agency explicit authority to do so is seen in some quarters as a missed opportunity. The FDA's Elizabeth Hillebrenner said that while the agency would prefer to regulate LDTs under new statutory authorities, the agency sees a public health problem with the current state of affairs, and thus, "we are moving forward with rulemaking."

VALID . LDT regulation

- LDT remain controversial
- Regulation of high-complexity testing top priority
- VALID or not, rules will come
- We should be actively involved in monitoring and staying informed
- No matter where you stand (Pro vs. Con)… the consequences will affect medical practice
- Once, the new version is release, we plan to host another **"test driving session"** and **examine changes**.