Rx Negotiation in BBB Spurs 'Clean' FDA User Fee Bill

VALID Act Removed, Other Provisions Like A.A. May Return

- **Late yesterday, the Senate HELP Committee ranking member Richard Burr (R-NC) released a "clean" FDA User Fee Reauthorization Act.** Bill text is here. The GOP version excludes the VALID Act, and the cosmetics and dietary supplement regulations that were integral to the Senate user fee package that was voted out of the HELP committee (13-9 vote) in June.

- **Bare bone bill unlikely passes as is….What comes back in, we ask?** See below for prior Senate common sense provisions that could come back into the fray for final passage.

    - **Accelerated Approvals (AA)**. Accelerated Approval granted FDA authority over requiring post-approval studies prior to approval, authority to specify the conditions for a post-approval study, allowing use of RWE, and laying out the same process for a withdrawal of an accelerated approval. The Senate wanted previously an intra-agency coordinating council within FDA to ensure appropriate use of accelerated approval.
    - **Therapeutic equivalence**.. The provision would require the FDA to make timely therapeutic equivalence evaluations for follow-on drugs approved through the 505(b)(2) pathway that have similar formulations as other approved products. This was not in the House User Fees.
    - **Domestic and Foreign inspection reporting requirements**. FDA would be required to publicly report information related to timeline of facility inspections. An annual report with respect to FDA domestic and foreign inspections and FDA recognition of foreign government inspections will also be required. These reporting requirements are also in the House User Fees.
    - **Orphan drug reforms**. A prior policy would beef up support for the development of orphan drugs, reversing a court ruling that prevents FDA from granting orphan exclusivity for separate populations.
    - **Multiple interchangeable Biosimilars**. FDA authority would be clarified to tentatively approve a subsequent interchangeable biosimilar biological product while a first interchangeable product's period of exclusivity is pending. Multiple products would be able to share a period of first interchangeable exclusivity if approved on the same day

- **Election year politics & Disenchantment over Drug reforms in BBB spur the clean FDA bill** The new text reflects the unresolved conflict over "Riders" so FDA User Fees can be reauthorized by Oct 1. Senator Burr remarked that "it's doubtful" that the current riders would remain intact in a final version of the bill. HELP Chair Murray (D-WA) still wants passage of the Senate FDA package, riders and all.

- **FDA User Fees usually receives bipartisan support, and RIF ("reduction in force") notices impact staff, morale but product reviews will continue to take place.** Negotiation discussion breakdown this late is unusual. Senate Burr mentioned the reconciliation (BBB) package as impacting Biopharma innovation in his press release, and the FDA reauthorization is yet another bill held hostage in negotiations – like USICA, the anti-China bill -- between the parties.

- **Lost opportunity: Even a "toothless" VALID Act will likely not make the cut in this year's FDA package, marking yet another delay to regulating a preponderance of diagnostic tests**

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in the US. We note there are more LDTs used in the market than FDA approved tests. We previously noted that the further changes to VALID may only require a fraction of so-called LDTs (those used by academic medical centers such as JHU, Mayo) to require regulatory review expected to start 2027.

- **OUR TAKE/NEXT UP: We think User Fees pass by Oct 1, even in a slimmed down version.** Patients and regulated industries would be disappointed not to have accelerated approval guardrails, CT diversity & modernization, real world evidence, manufacturing, as well as other important policies previously included. We note that FDA reviews will continue despite an agreement not being hatched: FDA Commissioner Rob Califf noted at a conference this week "we will review products as quickly as we can but the timelines go away and the commitment to the timelines go away…." (here) RIF notices may be not be issued even if an agreement is not reached in August. The FDA does have leftover funds to fund he agency for approximately 2-3 months. We expect that perhaps a few extraneous policies, like Accelerated Approval reforms, may get re-attached to this slimmed down bill.