# FDA User Fees Likely Pass With Budget Next Week

## "Clean" 5 Year Auth Likely, Policy Riders V. Possible at End of the Year

- **As negotiations drag on, the likelihood of a "clean" FDA user fee bill passing by Oct 1 increases.** The "four corners" of the Senate HELP and House Energy & Commerce Committees have been meeting since early September to hammer out a passable user fee package. The talks appear to have stalled, and Senate majority leader, Chuck Schumer (D-NY), said this week that the Senate is expected to continue working in October, cutting it close to the midterms. Senate Republicans are pushing for a clean five-year bill, but House and Senate leadership are reluctant to give up on policy riders that passed the House and previously had bipartisan support.

- **User fees have historically been bipartisan, but Senate Republicans are dissatisfied with Democrats & the agency.** Recall that the Senate user fee bill made significant progress until Burr announced his intent to focus on a clean passage in July after dissatisfaction with the *Inflation Reduction Act*. Republican members are also increasingly dissatisfied with the FDA over Monkeypox and opioids.

- **A clean package would include FDA User fee policies relating to Drugs, Medical Devices, Generics, and Biosimilars**. This includes PDUFA VII, MDUFA V, GDUFA III, BsUFA III. All programs will be funded 2023-2027 with an increased fee structure and existing reauthorization process / requirements. Product review timelines, hiring estimates, program enhancements are included.

- **The big riders – Orphan drug reforms & Accelerated Approval reform -- are expected to be dropped & possibly passed at year end**. But common-sense provisions to improve FDA review and increase access to biosimilars could still make the cut.

    - **Accelerated Approval reforms.** Senate AA provisions called for the creation of an intra-agency coordinating council within FDA to ensure appropriate use, granted FDA authority to require post-approval studies to be underway prior to approval, and laid out an approval withdrawal process if manufacturers failed to meet study requirements. The House passed AA reform provisions that grant FDA authority over post-approval studies and accelerated approval withdrawal, but also codifies additional labeling requirements for accelerated approval products.
    - **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.
    - **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.
    - **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.


Contact Ipsita Smolinski - 202.250.3741 - Ipsita@capitol-street.com

- **The VALID Act or PREVENT Pandemics Act, or both, could still pass before the end of the year, along with some mental health reforms.** The Senate's diagnostic reform is expected to be cut in a clean passage and the PREVENT Pandemics Acts stalled earlier this year. But to honor retiring Sen. Burr's (R-NC) work, either or both pieces of legislation may be revisited later this year for inclusion in an end of the year package.

    - **VALID Act grants the FDA pre-market authority to review and approve in vitro clinical tests (IVCTs), including laboratory developed tests (LDTs).** The effective date of the VALID Act, if passed, would be October 1, 2027, as the new rules will require user fees. FDA oversight would be based on a risk-based system. Definition of (1) High-risk, (2) Moderate-risk, and (3) low-risk tests are related to the health risks of an inaccurate test. Mitigating measures may shift LDTs into lower tiers of regulation and benefit manufactures. These measures include appropriate labeling, performance testing, submission of clinical data, and role of professionals. Technology certifications do not expire for multiple tests using the same underlying technology. High-complexity grandfathered tests will be unaffected by premarket review**.** the date of enactment are exempt from premarket review.

    - **Senate PREVENT Pandemic Act helps the US learn from COVID-19.** Retiring Sen. Burr's (R-NC) priority bill was shelved this summer, despite passing committee in March 2022. In their recent Monkeypox hearing, Senate HELP leadership confirmed that the PREVENT has not been abandoned. The bill is a catch-all and includes provisions that improve domestic manufacturing capabilities, modernize FDA, and establish pandemic mission control to improve federal response in the future.

    - **Mental health reforms could also be included in the year's end package**. This morning the Senate Finance Committee released a proposal at improving the mental health workforce. The bill seeks to increase psychiatric residency slots, expand Medicare's Health Professional Shortage Areas bonus program, establish a demonstration to increase mental health and substance use disorder providers in Medicaid, and establish Medicare coverage for marriage and family therapist services. The Senate Finance Committee has been building a mental health package for months with 2 other mental health provision drafts released earlier this year. In February 2022, the Committee announced 5 focus areas in mental health and released 2 discussion drafts: one on telemental, and one youth mental health. Parity and care integration are next to be addressed. Telemental Health Access to Care Act. The bill removes Medicare's in-person requirement for telemental, providers coverage for audio-only mental health services, and requires MA plans to provide transparency on OOP costs for mental health services. Improving Access to Physical and Mental Health for Children and Youth Under Medicaid and CHIP. This bill allows all providers to receive Medicaid reimbursement for behavioral and physical health services delivered on the same day, updates Medicaid guidance on mental healthcare in schools to clarify allowable payments, and expands Medicaid mental and physical health coverage for youth in public institutions.

- **OUR TAKE / NEXT UP: We expect a clean FDA 5-year reauthorization to pass this month on a 3-month continuing resolution that funds the government until December 16 – Policy riders may be added 4Q22.** FDA feels "reasonably" assured that funding will pass, Jeff Shuren, MD, director of CDRH, remarked that the division will proceed with the new performance goals, even if MDUFA V is not reauthorized on time. We note that PDUFA is the first to "run out" of funding and may not have the same flexibility if talks fall through. Even with no User Fee bill passage, workers will still be paid, but over time would likely miss PDUFA goals. Dr. Rob Califf, FDA Commissioner, notes that the agency has leftover funds to operate through October. In December, we could see (1) VALID Act (2) PREVENT Pandemics & possibly (3) FDA reforms e.g. Accelerated approval (4) some mental health reforms pass with an end-of-the year bill.


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