5 Year FDA User Fee Authorization

Dx FDA Pathway, Pandemic Preparedness, Accel Approval Reform Possible Dec 2022

Earlier this week, the Senate leadership unveiled the continuing resolution text. Summary of provisions are here. The government-funding bill (CR) contains clean User fees, Ukraine assistance, and extension of key programs until December 16th 2022, including the low-volume adjustment to Medicare hospital payments.

- **The CR text shows a clean package of FDA User fees 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 and requirements. Product review timelines, hiring estimates, and program enhancements are also included in the performance goal letter.

- **Key medical device and pharmaceutical programs are reauthorized until December 16th 2022.** These programs are critical for pharmaceutical and medical device R&D.
  - **Best pharmaceuticals for children** funds NIH studies of off-patent drugs in children.
  - **Humanitarian device incentive** grants humanitarian device exemptions to medical devices that benefit patients with rare diseases
  - **Single enantiomer exclusivity** authorizes the FDA to grant exclusivity for drugs containing single enantiomers.
  - **Critical Path Public-Private Partnership** allows the FDA to enter public-private partnerships to advance research and product development. We note that the recently announced Critical Path for Rare Neurodegenerative Diseases (CP-RND) is being convened by C-Path.
  - **Orphan drug grants** awards funding to clinical investigators working on rare disease products.
  - **Third party inspections program** authorizes accredited third parties to perform inspections of eligible device manufacturers.
  - Reporting on **pending generic drug applications and priority review application** was also reauthorized**.**

- **A clean user fees has ballooned the list of priorities that Congress must address in an end of the year package.**

  - **The VALID Act, in vitro clinical testing (IVCT) regulation, is likely to be revisited.** Congress has been working to regulate IVCTs, including laboratory developed tests (LDTs), for years. The increasing importance of LDTs during the pandemic has made it a major priority to be addressed in this legislative session. We noted that the Senate was taking the lead for passage this summer and we expect the chamber to continue their work at the end of the year.

  - **Starting in 2027, VALID sets up a risk-based system for FDA oversight of IVCTs.** A premarket, abbreviated premarket, and supplemental application review and approval process are outlined in the bill. We previously noted that the bill allows for several mitigating measures (appropriate labeling, performance testing, and role of professionals) which lowers oversight and benefits manufacturers. The bill also outlines several categories of pre-market review

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

exemptions including humanitarian exemptions, high-complexity grandfathered tests, low-risk IVCTs, low volume IVCTs, and modified IVCTs.

- **PREVENT Pandemics Act is another Senate end of the year priority.** The bill is a bipartisan, catch-all of roughly 37 different bills related to pandemic preparedness. The bill includes provisions to modernize FDA infrastructure, improve domestic biomanufacturing, establish a new office to oversee pandemic preparedness, improve public health data collection, and address healthcare workforce shortages.

- **Congressional focus on mental health this year will likely lead to some mental health reform provisions in the year-end package.** We previously noted that Senate Finance Committee has been building a mental health package for months with 3 mental health bill drafts released earlier so far. They include proposed reforms like eliminating Medicare's in-person requirement for telemental services, updates to Medicaid guidance on mental healthcare in schools, and establishing Medicare coverage for marriage and family therapists.

- **Some FDA riders are expected to be revisited in end of the year discussions.** Notable FDA priorities to be addressed include

  - **AA reform.** Accelerated approval reform provisions included in House passed user fees allows the FDA to require post-approval studies, which may be supported by real-world evidence, to be underway at the time of approval and allows the FDA to withdraw approvals where sponsors fail to conduct studies with due diligence. The Senate text called for the creation of an internal oversight committee to monitor FDA's use of accelerated approvals in addition to these requirements.

  - **Clinical trial diversity reform.** Clinical trial reform provisions called for manufacturers to be required to submit a diversity action plan and for the FDA to be required to provide guidance on use of RWE and use of decentralized CTs, and host public workshops to enhance clinical trial diversity.

  - **Generic flexibilities.** Provisions like changes to the proposed labeling requirements and allowing the FDA to provide generic manufacturers info on ingredient differences aim to improve generic approval process.

NEXT STEPS: We predicted a clean 5-year FDA reauthorization to be attached to the 3-month continuing resolution. A 72-23 Senate cloture vote 9/27 started the process for passage this week. We expect the CR to pass before Friday, the September 30 deadline. The package not only funds the government until December 16th, but also limits the extension of key FDA programs. The limited extensions are intended to incentivize Republicans to return to negotiation table for end of the year riders in December. But the list of priorities that need to be resolved has grown bigger (FDA reforms, VALID Act, mental health reform, and PREVENT Pandemics Act). With this many competing health priorities, only a select number of the FDA riders are expected to pass this year.

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