Top Health Policy Issues in 2017

:

Prescription Drug User Fee Act (PDUFA) Reauthorization

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What Are User Fees?

A well-funded, science-based FDA and consistent, predictable and transparent product review processes are critical to and necessary for biomedical investment, innovation and improvements in patient care.

- "User Fees" are private monies paid to FDA by industry to support product review activities
  - The agreements negotiated between industry and FDA aim to ensure faster, more predictable approval times, and specify that user fees are intended to supplement rather than replace congressionally appropriated funding to FDA.
- 1992: Prescription Drug User Fee Act – PDUFA
  - Renewed in 1996, 2002, 2007, 2012
- 2002: Medical Device User Fee Act – MDUFA
  - Renewed in 2007, 2012
- 2012: Biosimilars User Feet Act – BsUFA
- 2012: Generic Drug User Fee Act – GDUFA
- *Also: animal drugs, animal generic drugs & tobacco*

Why User Fees?

- FDA relies heavily on user fees to supplement congressional appropriations for its product review activities – for PDUFA VI & MDUFA IV:
  - Human Drugs & Biologics: ~80% user fees
  - Devices & Diagnostics: ~30% (approx. one-third) user fees
  - *"Orphan Drug" applicants are exempt from paying user fees – but FDA still relies on appropriations and user fees to conduct reviews of Orphan Drug candidates*
- FDA User Fee "reauthorization" bills are considered "must-pass" legislation
  - Vehicle for additional FDA-related legislation or "riders"
- 2012: FDA Safety and Innovation Act (FDASIA) renewed FDA's authority to collect user fees, and made improvements to regulatory review processes
  - Increased industry-paid user fees to support regulatory system & process improvements
  - Included several provisions to advance rare disease innovation:
    - Established Breakthrough Therapy Designation (Advancing Breakthrough Therapies for Patients Act)
    - Established use of surrogate endpoints & accelerated approval for rare disease therapies(ULTRA/FAST Act)
    - Created Rare Pediatric Disease (RPD) Priority Review Voucher program (Creating Hope Act)

What's Next for User Fees?

- September 30, 2017: FDA's current authority to collect user fees expires
  - RIF notices before August Recess

- Wildcard Considerations:
  - Partisan/gridlocked Congress
  - New/Trump Administration
  - New TBD FDA Commissioner

- A delay or total failure to renew PDUFA will likely:
  - Hinder FDA from conducting full range of review activities
  - Disrupt the progress of necessary regulatory process improvements under *FDASIA* and *21st Century Cures Act*
  - Slow product review times, increase regulatory unpredictability
  - Further aggravate an already significant downturn in life sciences venture capital investment
  - Delay patient access to innovative new technologies

Questions?

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