Food and Drug Administration (FDA) User Fee Objectives

Strengthen Biosimilar and Generic Competition

1. **Eliminate the Statutory Distinction Between the Approval Standard for Biosimilar and Interchangeable Biosimilar Products and Deem that Approved Biosimilars are Interchangeable (FDA request for FY26)**

   Current Issue: Biosimilar manufacturers that want their products to be interchangeable with branded biologics must conduct additional clinical studies called "switching studies." These studies are no longer needed as biosimilars have been shown to be just as safe and effective as their respective reference products.

   Proposal: Congress should codify the FDA's guidance that no longer requires an additional clinical trial to demonstrate a biosimilar's interchangeability with its reference product. Legislation should continue to provide flexibility to the FDA to require these studies in certain instances.

2. **Require Proactive Purple Book Patent Listing for Biologics**

   Current Issue: Companies are not required to disclose as much information on biologics patents and exclusivities as small molecule drugs. The Hatch-Waxman Act requires sponsors of small-molecule drugs to list patents they own or license when they receive approval for their product. The same requirement does not apply to biologics and the Purple Book.

   Proposal: The FDA should publish timely updates to the Purple Book and ensure that the Purple Book includes more complete data on FDA-licensed biological products, such as patents and exclusivities from the time of licensure going forward.

3. **Explicitly Address Generic Drug-Device Combination Products to Remove Barriers for Product Development (FDA request for FY25)**

   Current Issue: The Federal Food, Drug, and Cosmetic Act (FD&C Act) does not explicitly address abbreviated new drug applications (ANDAs) for drug-device combination products, and the lack of clarity makes it difficult for companies to develop generic versions of these products and for the FDA to efficiently approve ANDAs.

   Proposal: Congress should amend the FD&C Act to explicitly address the submission and review of ANDA applications for drug-device combination products, as well as drug products submitted in an ANDA that are used with a device. Congress should also make clear that the FDA can request and review data for these applications, that some differences between the device parts of the reference listed drug (RLD) and the proposed generic are allowed, and that labeling differences resulting from those allowed device differences are acceptable.

4. **Amend the 3-Year Exclusivity Provisions for New Drug Products that Contain a Previously Approved Active Ingredient to Encourage Meaningful Innovation and Timely Competition (FDA request for FY25)**

   Current Issue: New drugs can qualify for exclusivity that can block or delay competition even when the new drug applicant is not seeking exclusivity, or when the new clinical investigation supporting that exclusivity does not show the hypothesized effect of the drug.

   Proposal: Congress should limit the Hatch-Waxman 3-year exclusivity provisions to cases where it is (1) affirmatively sought after by the manufacturer and (2) supported by data demonstrating the hypothesized effect of the drug. It should also prevent new safety information and resulting labeling updates from extending exclusivity and blocking competition. This approach would continue to reward innovation, while also allowing for earlier access to generic drugs in certain situations.

5. **End Sham Citizen Petitions**

   Current Issue: There is widespread, strategic misuse of citizen petitions by drug companies striving to hold off competition. The FDA is required to rule on petitions filed by interested parties, including competing pharmaceutical manufacturers seeking to block the approval of generics, biosimilars, or novel therapies based on supposed safety concerns.

   Proposal: Congress should 1) strengthen the FDA's authority to dismiss petitions and penalize non-meritorious filers by instituting time limits and associated penalties and 2) improve the transparency of the FDA's review of citizen petitions by requiring the agency to report more details about delays and the agency's review process. Congress should also empower the FTC to penalize brand drugmakers who file "sham" or baseless citizen petitions to the FDA.

Improve Post-Market Surveillance and Coverage of Drugs and Devices

6. **Expand the FDA's Mandatory Recall Authority to Cover All Drugs (FDA request for FY25)**

   Current Issue: The FDA has the authority to mandate recalls for controlled substances in certain circumstances: for biological products and cosmetics. The agency lacks mandatory recall authority for other human drugs. Currently, the great majority of companies agree to recall their drug products when asked to voluntarily do so by the FDA. However, there are cases where a company extensively delays initiating a recall or refuses to recall a violative drug product when asked to do so.

   Proposal: Expand the FDA's mandatory recall authority to all human drugs, which would help remove drug products from the market more quickly and reduce harm to consumers.

7. **Further Strengthen the Accelerated Approval Program**

   Current Issue: Congress recently granted the FDA additional tools to help ensure accountability and the completion of confirmatory trials for those products granted accelerated approval. However, more can be done to strengthen the program and help protect patients.

   Proposal: Congress should grant the FDA the authority to automatically withdraw accelerated approval drugs or indications when the confirmatory trial does not show that the product has clinical benefit, and require confirmatory trial protocols to be finalized as a condition of accelerated approval.

8. **Use Post-Market Monitoring to Strengthen the FDA Surveillance of All Approved Drugs**

   Current Issue: Between 2016 and 2024, over two-thirds of novel drugs were approved with postmarketing requirements (PMRs), but only one-third completed those requirements on time. For those drugs that completed their PMRs, over 60% of them required further labeling changes, which could include new pertinent safety information.

   Proposal: To help the FDA ensure these PMRs are met, Congress should (1) set measurable completion benchmarks for timely study completion, aligning agency accountability for post-approval evidence generation with that is already in place for review efficiency; (2) require public reporting of study outcomes, including whether studies resulted in labeling changes, safety communications, or product withdrawals; and (3) require disclosure of delays and rationale for delayed or terminated studies, with regular updates accessible through a centralized, publicly searchable database linking drugs to their associated postmarketing studies.

9. **Make Medicare Coverage of New Devices Align With Available Clinical Evidence**

Current Issue: Two recently introduced bills of concern propose providing automatic Medicare coverage to breakthrough devices for 4 years. Breakthrough devices already account for most new technology add-on payments from Medicare, and these bills could substantially increase Medicare expenses. They could also lead to low-value or potentially harmful spending and utilization of devices that come to market with less rigorous evidence supporting their use.

Proposal: Medicare national coverage determinations should be made through an evidence-based process to determine whether items and services are reasonable and necessary for the diagnosis or treatment of an illness or injury. Statutes allow certain flexibilities, such as local coverage determinations and coverage with evidence development. Ultimately, the process should be evidence-driven and aim to provide patients with a product or service that has been shown to provide clinical benefit.

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