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Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

(Submitted to https://www.regulations.gov/commenton/FDA-2025-N-0816-0001)

Re: Comments regarding the beginning of negotiations regarding PDUFA VIII (Docket No. FDA-2025-N-0816)

To Whom It Concerns:

Public Citizen is a nonprofit consumer advocacy organization with more than 500,000 members. As follow-up to the recent Food and Drug Administration (FDA) kickoff meeting about the anticipated five-year reauthorization of the Prescription Drug User Fee Act (PDUFA) discussion, we suggest the following process change and agenda items:

Necessary process change:

> In contrast to previous PDUFA reauthorization talks and negotiations, **the upcoming negotiations should afford full and equal participation to non-industry participants**, including consumer and patient advocacy organizations such as ours. Presently, industry negotiations with the FDA control the process and are mostly closed to the public, completely excluding non-industry members from the FDA–industry negotiating meetings. This must be remedied to make the process appropriately transparent and more patient oriented.

Important agenda items:

1. The FDA should create a budget justification to **expand Congressional appropriations for the Center for Drug Evaluation and Research** and the **Center for Biologics Evaluation and Research** such that user fees can be greatly reduced as a proportion of the operating budgets from their current level to as close to zero as possible. At present the revenue to

maintain FDA's drug-approval effort is too dependent on quid pro quo payments from the regulated industry.

2. The FDA should seek congressional support **to develop annual metrics to assess the performance of the drug-approval process that are patient oriented**. Examples of such metrics include:
    a. Estimates of morbidity and mortality benefits (or losses) from recently (e.g., rolling averages over the past five years) approved medications.
    b. The proportion of new approvals based on at least two favorable and consistent, randomized, controlled clinical trials.
    c. The proportion of approvals where FDA's scientific staff and leadership were in agreement regarding such decisions.
    d. The proportion of approvals that were reviewed by an external, expert advisory committee and whether the advisory committee vote agreed with the final decision of the FDA.

3. The FDA should seek Congressional **funding and support to bolster its efforts to see that almost all approval decisions are supported by** at least two consistent, phase 3 randomized controlled trials.

4. The FDA should seek **Congressional funding and support to limit the use of accelerated approval and other fast-track pathways**.
    a. In rare instances where such fast-track pathways are used, they should always require external advisory committee review before a final decision is made by the FDA regarding approval.
    b. When accelerated approvals occur, mandated post-marketing studies must be completed on schedule and they must confirm reasonable safety and effectiveness. Otherwise, the FDA should have the authority to revoke the approval.

5. The FDA should seek Congressional appropriations **to strengthen and reaffirm the agency's commitment to timely, rigorous, in-person inspections** of manufacturing facilities to ensure the safety and quality of prescription drugs.

6. The FDA should **seek from Congress the authority and necessary budgetary resources to recall prescription and over-the-counter drugs, when the agency determines that a recall is needed** (for example, see the Protecting Americans from Unsafe Drugs Act, which was introduced by Rep. Andy Kim and passed by the House as part of H.R. 4521, the America COMPETES Act of 2022).

7. The FDA **should request from Congress the budgetary resources to guarantee and confirm that all phase 3 human clinical trials are sufficiently inclusive of racial, ethnic,**

and other subgroups that compose the U.S. population. Phase 3 trials must be sufficiently powered so that they can confirm a drug is safe and effective in all subpopulations listed on the product label; otherwise consumers in those subgroups should be cautioned that the prescribing information may not similarly apply to them. Moreover, the FDA should establish metrics to confirm that their drug development pipeline is reasonably inclusive of potential remedies for diseases that impact certain subpopulations (e.g., sickle cell disease).

8. **The FDA should create a firewall between the scientists who conduct the final review of medical products and other staff who offer pre-application submission support and instructions** to applicants and thus may be inclined to advocate on behalf of the sponsor.

Thank you for your attention to these suggestions. Public Citizen strongly encourages the FDA to use all these important proposals for the PDUFA reauthorization talks moving forward.

Sincerely,

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