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Testimony at the FDA's public meeting on Prescription Drug User Fee Act (PDUFA) Reauthorization

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I'm Michael Abrams, Senior Health Researcher with Public Citizen. I have no financial conflicts of interest related to PDUFA.

The draft commitment letter, like previous ones, does not address many patient and consumer concerns. The absence of public-health–oriented measures remains a critical deficiency. Here is a short list of measures that should be added to the commitment letter:

For each newly approved medication, including supplemental approvals, FDA performance measures should include consideration of:

- The number of clinical trials reviewed, and how many were positive and how many were not
  - Timely posting of all trials on clinicaltrials.gov
  - A record of the time to posting of review documents at Drugs@FDA (after approval, in days)
- A flag (or flags) indicating whether the trial participants were sufficiently representative of the U.S. population for age, race, and gender
- A flag indicating whether the approval decision was unanimous among: FDA scientists, FDA leadership, and external advisors

For medications approved in the most recent year or in prior years:

- Information on outcomes, including withdrawals, recalls, warnings, missed PMR (post-marketing report) deadlines, fraudulent marketing, and other adverse events

The FDA should facilitate independent evaluation of all these data to grade the agency's performance in regulating prescription drugs.

Although these are reasonable asks of the FDA's drug approval program, such performance measures have been mostly ignored during the latest user-fee negotiations and in the draft commitment letter. Adjustments to the "commitments" might help

address ongoing concerns about “industry capture” of the FDA and other deficiencies that harm prescribers and consumers.

Thank you.

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