Doctors for America FDA Task Force Asks Congress to Include FDA Reforms in End-of-Year Package

The Doctors for America FDA Task Force is urging Congress to **include critical FDA reforms in an end-of-year omnibus package**. Earlier this fall, when Congress stripped these provisions from the FDA user fee reauthorization package and instead passed a 'clean' reauthorization, Congressional leadership pledged to revisit the stripped out patient-centered provisions during the lame-duck session. With time running out in the 117th Congress, Doctors are calling on Congress to take action before the end of the year to help ensure the drugs and therapeutics we prescribe our patients have been proven to be both safe *and* effective. Doctors from around the country are calling on Congress to include the following patient-centered improvements in any end-of-year legislation:

Reform the FDA's Accelerated Approval Pathway

Now is a pivotal time to strengthen the regulatory review process to ensure that FDA approval of prescribed drugs provides the assurance of true clinical benefit and safety for both patients and clinicians. There is an opportunity to achieve the right balance between offering earlier access to treatments under the accelerated approval pathway and ensuring confirmation of their safety and efficacy.

In June, the House passed a user fee package (H.R. 7667) which included these critical reforms to the accelerated approval pathway. Both the House and Senate should now work to ensure that these critically important patient protections are added to the omnibus.

We urge Congress to include H.R. 7667's Sec. 804 "Postapproval studies and program integrity for accelerated approval drugs" in the omnibus.

Ensure Clinical Trial Diversity

Clinical trials are a vital component of evidence-based medicine, and trial outcomes inform medical decisions at every stage of care. However, according to the FDA's 2015-2020 Drug Trials Snapshot Summary Reports, minorities are on average significantly underrepresented in clinical trials[1]. For drugs to be proven safe, effective and included as standard of care in clinical guidelines, the inclusivity of racially and ethnically diverse patients in clinical trials is paramount. This will also help generate trust in biomedical research amongst the public and increase the health of underrepresented populations.

The House-passed user fee package (H.R. 7667) included crucial provisions to enhance diversity and equity in clinical trials to strengthen patient protections and to amplify transparency within the agencies approving therapies.

We urge Congress to include all of H.R. 7667's Title V (Sec. 501- 506) "Improving Diversity in Clinical Trials" in the omnibus.

About Us

Doctors for America is an independent organization of more than 27,000 physicians and trainees across the country working together to ensure patients affordable access to truly effective and safe healthcare. Doctors For America's FDA Task Force, comprised of over 30 physicians across specialties, works to support and strengthen the FDA so that it can continue to provide physicians and patients with two main assurances: that therapeutic approvals are free from an undue conflict of interest and they rely on the highest evidentiary standards. We are asking Congress to update FDA's Accelerated Approval Program to protect our patients.

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[1] Center for Drug Evaluation and Research. "Drug Trials Snapshots." U.S. Food and Drug Administration, FDA, https://www.fda.gov/drugs/drug-approvals-and-databases/drug-trials-snapshots.