

Summary:

Addressing the Exclusion of Persons with Obesity in Clinical Trials and Drug Labeling

The exclusion of individuals with obesity from clinical trials has become a critical issue recognized by the FDA. Despite the high prevalence of obesity (42% of U.S. adults), people with this condition are often excluded from studies evaluating medications for conditions other than obesity. This exclusion creates two significant challenges: a lack of diversity in clinical trials and deficient drug labeling that does not assure the safe and effective use of these medications in persons with obesity.

First, the absence of individuals with obesity in clinical trials leads to a lack of data on how these medications perform in this population. This undermines the diversity and inclusivity of clinical trials, making it difficult to assess the appropriate dosages, efficacy, and potential side effects in persons with obesity. Medications may interact differently in people with obesity due to variations in body fat composition, metabolism, drug distribution, and elimination. Failing to study these differences can jeopardize the safety and effectiveness of treatments for a significant portion of the population.

Second, the exclusion of persons with obesity from trials leads to inadequate drug labeling, leaving healthcare providers without sufficient information to properly prescribe medications to patients with obesity. Examples of this deficiency include **posaconazole**, an antifungal medication, and **brexpiprazole**, an antipsychotic drug. In both cases, drug labels fail to provide clear guidance on dosing or safety considerations for individuals with obesity. This can lead to either under-dosing, which reduces the effectiveness of the medication, or dosing might create problems because of slow clearance of a drug like posaconazole in persons with obesity. Without specific recommendations for this population, physicians are left to make educated guesses, potentially putting patients at risk.

To address this problem, the FDA must act on two fronts. First, they should require drug makers to include persons with obesity in clinical trials for all medications, ensuring that clinical data reflects the full spectrum of the population who may use these drugs. This will provide clinicians with a better understanding of how to safely and effectively treat patients with obesity. Second, the FDA should mandate that pharmaceutical companies update the labeling of existing drugs, like posaconazole and brexpiprazole, to include specific guidance on their use in persons with obesity. Doing so would improve the safety and efficacy of these drugs and reduce health disparities for individuals with obesity.

By enforcing more inclusive clinical trial designs and updated drug labeling, the FDA can help ensure that all patients, including those with obesity, receive evidence-based care tailored to their needs.

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