COMMENTARY

The FDA Initiative to Assure Racial and Ethnic Diversity in Clinical Trials

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On April 13, 2022, the Food & Drug Administration (FDA) issued a new draft guidance for industry for "developing plans to enroll more participants from underrepresented racial and ethnic populations in the U.S. into clinical trials ." In so doing, the FDA reaffirmed the reality that racial and ethnic minorities remain underrepresented in clinical trials. FDA Commissioner Robert M. Califf, MD offered that the "U.S. population has become increasingly diverse, and ensuring meaningful representation of racial and ethnic minorities in clinical trials for regulated medical products is fundamental to public health." Commissioner Califf went on to pledge that "achieving greater diversity will be a key focus throughout the FDA to facilitate the development of better treatments and better ways to fight diseases that often disproportionately impact diverse communities." This Commentary is dedicated to a thorough review of the new FDA policy and the implications thereof. (J Am Board Fam Med 2023;36:366–368.)

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On April 13, 2022, the Food & Drug Administration (FDA) issued a new draft guidance for industry for "developing plans to enroll more participants from underrepresented racial and ethnic populations in the US into clinical trials."[1] In taking this step, the FDA reaffirmed the reality that racial and ethnic minorities remain underrepresented in present day biomedical research.[1] Comments offered by FDA Commissioner Robert M. Califf, MD attested to the fact that the "US population has become increasingly diverse, and ensuring meaningful representation of racial and ethnic minorities in clinical trials for regulated medical products is fundamental to public health."[1] Commissioner Califf went on to pledge that "achieving greater diversity will be a key focus throughout the FDA to facilitate the development of better treatments and better ways to fight diseases that often disproportionately impact diverse communities."[1] For practitioners of family medicine, this has particular import – while many family medicine physicians may not be involved routinely in large-scale clinical trials, the outcomes of these trials have direct bearing on the treatments and practices available to an increasingly diverse patient population. Moreover, patient participation in clinical trials is "strongly influenced by sustained racial disparities in health, limited access to health care, and negative encounters with health care providers."[2,3] In this *Commentary* we review the backdrop for the new FDA policy, highlight its key recommendations, and discuss the implications thereof.

Recent FDA data suggest that of the 32,000 individuals who participated in new clinical drug trials in the US in 2020, a total of 8% were Black.[4] The relative representation of Asian and Hispanic participants was limited to 6% and 11%, respectively.[4] These estimates diverge markedly from those of the 2020 US Census according to which Black Americans, 41.1

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million in all, accounted for 12.4% of the US population.[5] Asian and Hispanic Americans, in turn, comprised 7.2 and 18.7% of the US populace, respectively.[5] The underrepresentation of minorities in clinical drug trials (as demonstrated in the 2020 study) is both morally unfair and scientifically mistaken in that the racial and ethnic minority groups in question bear a disproportionately higher prevalence of chronic diseases.[1] The new FDA draft guidance for industry, 1 wherein the submission of a "Race and Ethnicity Diversity Plan" is obligatory, constitutes the latest effort on the part of the FDA to address what has been a glaring case of inequity.[1] It is paramount that enrollment in clinical trials reflect the diversity of the US population in that any and all elements of society are destined to rely on the ensuing therapies.[1]

The impediments to the participation of racial and ethnic minorities in clinical trials are multifarious. Mistrust in the very integrity of the clinical research apparatus due to past abuses is often at play.[1] The infamous United States Public Health Service Syphilis Study at Tuskegee, wherein nearly 400 African American men went untreated for a total of 40 years, is frequently cited. Such atrocities give historic weight and context to the present-day inequities and racism many patients experience, hardening their skepticism and distrust of the health care system overall.[3] Additional barriers noted by the FDA to the participation of racial and ethnic minorities in clinical trials include

- inadequate recruitment and retention efforts
- frequency of study visits
- time and resource constraints for participants
- transportation difficulties
- language and cultural differences
- health literacy
- religion
- limited access within the health care system
- lack of awareness and knowledge about what a clinical trial is and what it means to participate.[1]

Not until the early nineties did the US Congress attempt to address the long-standing challenges of the clinical drug trials. Relying on the *National Institutes of Health Revitalization Act of 1993* as its legislative vehicle, Congress called for the "inclusion of women and racial and ethic minorities as subjects in each federally funded clinical research project under title IV." The law also saw to the establishment of the Offices of Research on Women's Health and Minority Health at the National Institutes of Health. The above notwithstanding, the challenge of diversifying the clinical trial enterprise of the FDA continued unabated. A recent analysis by Turner et al. concluded that over the past 2 decades, the majority of US trials in ClinicalTrials.gov did not report race/ethnicity enrollment data, and that minorities were underrepresented in trials with modest improvement over time.[6]

It was not until 2014 that the FDA formulated a 27-point 5-year action plan designed to boost clinical trial participation by women, minorities, and older adults. The 5-year plan required the FDA to work with "industry, advocacy groups, and other stakeholders to standardize subgroup categories, develop strategies to attract participants, and improve the quality of subgroup analyses in new drug applications." Comments offered by then FDA Commissioner Margaret A. Hamburg, MD acknowledged that "richer information is collected when different subgroups are enrolled in pivotal studies for medical products." By 2016 the FDA issued new recommendations to industry as to the collection of race and ethnicity data in clinical trials.[1] Comparable recommendations were issued by the FDA in 2017 with medical devices in mind.[1] Further guidance intent on enhancing diversity in clinical trials was issue by the FDA as recently as November 2020.[1]

The new FDA draft guidance, *Diversity Plans to Improve Enrollment of Participants from Underrepresented Racial and Ethnic Subgroups in Clinical Trials*, requires sponsors of medical products to submit a "Race and Ethnicity Diversity Plan" to the agency early in clinical development.[1] Sponsors of medical products would do well to submit their "Diversity Plans" at the time of submission of the *Investigational New Drug* or of the *Investigational Device Exemption* application.[1] Overall support for this latest FDA initiative is to be afforded by the FDA *Office of Minority Health and Health Equity* through an "ongoing public education and outreach campaign."[1] Although the new draft guidance was developed primarily by the FDA *Oncology Center of Excellence*, significant input was also afforded by the *Center for Drug Evaluation and Research*, the *Center for Biologics Evaluation and Research*, and the *Center for Devices and Radiologic Health*.[1] It follows that the new guidance applies to all the medical products which fall under the jurisdiction of the FDA.[1]

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Underscoring this critical shortcoming in clinical research, the release of the latest FDA draft guidance for industry on the racial and ethnic diversity of clinical trials coincided with the publication of a similarly focused Report of the National Academies (*Improving Representation in Clinical Trials and Research: Building Research Equity for Women and Underrepresented Groups*).[7] Keeping the FDA in its sights, the National Academies Report recommends that the agency "require study sponsors to submit a detailed recruitment plan that explains how they will ensure that the trial population appropriately reflects the demographics of the disease or condition under study."[7] The National Academies make further recommendations aimed at holding research sponsors accountable to these enrollment targets, including having local Institutional Review Boards require that the representativeness of clinical trials be 1 measure in the research design for the protection of human subjects. The Report also advises Congress to direct the FDA to establish a taskforce to study new incentives for trials that achieve representative enrollment.[7]

The latest FDA draft guidance to industry is to be lauded as a step in the right direction. However, its impact on the representation of racial and ethnic minorities in clinical trials will only become apparent over time. Lacking the force of law, the latest initiative merely offers recommendations and could well fail like its multiple predecessors. It may be time for Congress to step in to bolster the efforts to assure racial and ethnic diversity in clinical trials by addressing in statute some of the social determinants of health. Bills such as the *DIVERSE Trials Act*[8] provide for (among other things) incentives and education programs to diversify clinical trials, and the *Diverse and Equitable Participation in Clinical Trials (DEPICT) Act*[9] authorizes the FDA to issue regulations to this end. Only in taking such steps to hold the research apparatus accountable can 1 be assured that meaningful racial and ethnic diversity of patients and their broader communities is fully represented in clinical trials.

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