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LETTER TO THE EDITOR

Ensuring Black Lives Matter in Drug Development

William E. Fitzsimmons, Pharm.D., M.S.[1,2,4] · Clara Okorie-Awé, Ph.D., Ed.D.[3]

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Recent events surrounding the Black Lives Matter movement has led many CEOs of biopharmaceutical companies to speak out against racial injustice wherever it is seen [1]. The support and action of these leaders is critical to making a difference on this issue within the pharmaceutical industry.

It has long been recognized that Blacks are underrepresented in clinical trials in oncology, rheumatology, and cardiology [2, 3, 4, 5]. This is despite having a higher incidence of many diseases including diabetes, hypertension, asthma, sarcoidosis, stroke, and myeloma.

We assessed the novel therapeutic drugs approved in the US so far in 2020 and identified 20 drugs where the FDA has posted their review documents. These Reviews were searched for data on race including Black or African American. Blacks comprised > 10% of the active treated population in only 5/20 (25%) of the approvals. Of the 8 oncology drugs, 7 (88%) described efficacy assessments in less than 10 Black patients, which was also less than 10% of the trial population. Representation in oncology studies is particularly important since Blacks have the highest death rates and shortest survival for most cancers and Black men have the highest cancer incidence.

In some reviews, the FDA noted higher rates of adverse events or lower drug exposure in Black patients, however their ability to draw conclusions were limited as evidenced by statements such as: "The slightly higher incidence of TEAEs (treatment emergent adverse events) among black patients is likely not significant given the small numbers of black patients enrolled in the clinical studies," or "There were insufficient African American patients for any comparative analyses," or "…this reviewer notes that the safety population is almost entirely white and worries that this may limit the generalizability of the results." Although these limitations were described by the FDA reviewers, there were not Post-Marketing Commitments (PMCs) to study additional Black patients. It is paramount that we not delay the availability of innovative new therapies, but if there are inadequate representation of Blacks or other relevant groups this could be addressed in labeling so that prescribing clinicians are aware and also in Phase 4 commitments to help ensure that these data are collected post-approval. Generating these data are important since it is known that there are examples of pharmacogenetic (e.g. CYP3A5 metabolism, G6PD deficiency) and pharmacodynamic (e.g. response to various antihypertensives) racial differences that may impact dosing, efficacy and safety of drugs in Blacks.

The FDA has stated that the demography of trial participants should reflect the intended use population and they require that each sponsor provide sufficient data to evaluate the safety and efficacy for the intended population and also require analyses by race in the New Drug Applications. However there is no law or regulation for the inclusion of racial subgroups in the clinical trials.

In Section 907 of the 2012 Food and Drug Administration Safety and Innovation Act, Congress directed the FDA to examine the inclusion and analysis of demographic subgroups including race, in applications for drugs, biologics, and devices. As a result, in 2014 "FDA Action Plan to enhance the collection and availability of demographic subgroup data " was published. The report contains many excellent suggestions regarding completeness, quality, and transparency of demographic subgroup data and also identification of, and strategies to overcome, barriers to clinical trial participation. However, it is evident from current new drug approvals that re-examination is warranted to ensure that Black patients have access to clinical studies of innovative therapies and are appropriately represented in efficacy and safety data. The biopharmaceutical industry, clinical trial investigators, contract research organizations, and the

✉ William E. Fitzsimmons
wfitzsim@uic.edu

[1] Department of Physiology and Biophysics, College of Medicine, University of Illinois at Chicago, Chicago, USA

[2] Tutela Pharmaceuticals Inc, Vernon Hills, IL, USA

[3] Diversity and Inclusion, College of Pharmacy, University of Illinois at Chicago, Chicago, USA

[4] Vernon Hills, USA

FDA all play crucial roles. Great strides have been made in advancing drug development in pediatric patients and drug labeling to include geriatrics; perhaps some of these same approaches can be used to address racial inequity in drug development. Is it time to leverage the learnings from the Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act to create a Racial Equity in Development Act?

To ensure that Black Lives Matter, we must strive to address and correct factors that contribute to a low willingness of Blacks to participate in clinical trials. There is a need to address why Blacks are reluctant to participate in clinical trials (mistrust and fear, socio-cultural barriers, and others). In 2018, the National Black Church Initiative (NBCI) with 15.7 million members called on the FDA to mandate diversity in all clinical trials. We think it is time to consider this clarion call to action. Perhaps partnership with entities such as NBCI is warranted.

The urgency in addressing underrepresentation of Blacks in clinical trials is highlighted by the current COVID-19 pandemic. Numerous new therapies and vaccines are under development. It is vital that these trials are representative of the Black population since emerging evidence indicates that Blacks have higher rates of hospitalization and deaths from this virus compared to Whites.

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