

## Correspondence

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

*To the Editor:* We greatly appreciate the work of Adashi and Cohen and strongly agree with the importance of increasing diversity and representation of all groups of Americans within biomedical research. As previously stated, inclusion of minority groups within clinical trials is likely to improve results and findings for a demographic of people who disproportionately carry the burden of many of our country's chronic diseases.<sup>1</sup>

Although Adashi and Cohen discuss factors of mistrust of the government within the African American population that has roots in the infamous Tuskegee Syphilis Trials, we would like to expand on this mistrust within the Hispanic/Latino community. Hispanic Americans are the largest racial minority in the country representing 18.7% of the population, yet comprise of only 11% of research participants.<sup>2,3</sup> This 7.7% discrepancy is the largest among racial minorities in the country. Studies show that there are approximately 21 million immigrants of Hispanic origin in the United States, of which over 7 million are undocumented.<sup>4</sup> It is well established that there is a high level of mistrust among the undocumented Hispanic community with the United States Health care System often due to fears of deportation.<sup>5</sup> It is highly likely this mistrust encompasses biomedical research and dissuades this demographic from participation. In addition, high rates of uninsurance among undocumented immigrants leads to less engagement with the health care system overall.<sup>6</sup> Participation in federally funded clinical trials is often free of charge or can even reimburse subjects, yet a misunderstanding of the costs associated with participation in clinical trials may be a contributing factor in the relatively low rates of Hispanic Americans in clinical research.

Family medicine physicians are on the frontlines when engaging with this patient population and may often be their only point of contact with the health care system. It is imperative that family medicine physicians understand this dynamic and the role that they can play in reducing the discrepancies in research participation. This starts with establishing meaningful interactions with patients and developing relationships built on trust within this community. This ground-up approach may then begin to erode the mistrust of the health care system that is often

times ingrained within this community. In addition, family medicine physicians must take meaningful steps to educate this patient population on the accessibility of clinical trials regardless of insurance status. By taking these steps, these physicians can make a significant impact on the lives of marginalized communities and begin to lessen the underrepresentation of these groups in clinical research.

Forrest Bohler, BS  
Nikhil D. Aggarwal, BS  
and Garrett W. Peters, BS

From the Oakland University William Beaumont  
School of Medicine, Auburn Hills, MI  
E-mail: [lforrestbohler@yahoo.com](mailto:lforrestbohler@yahoo.com)

To see this article online, please go to: <http://jabfm.org/content/00/00/000.full>.

### References

1. Adashi EY, Cohen IG. The FDA initiative to assure racial and ethnic diversity in clinical trials. *J Am Board Fam Med* 2023;36:366–8.
2. Drug Trials Snapshots. Summary report. February 2021. Available at: <https://www.fda.gov/media/145718/download>.
3. United States Census Bureau. 2020. Census illuminates racial and ethnic composition of the country. August 12, 2021; Available at: <https://www.census.gov/library/stories/2021/08/improved-race-ethnicity-measures-reveal-united-states-population-much-more-multiracial.html#:;:text=Black%20or%20African%20American%20Population,The%20Black%20or&text=In%202020%2C%20the%20Black%20or,million%20and%2012.6%25%20in%202010>.
4. CMS (Center for Migration Studies). 2022. Democratizing data initiative: undocumented immigrants in the United States, by state, race, and year, 2010-2019 [dataset]. New York, NY: CMS. Available at: <https://www.cmsny.org/data-undocumented-state-race-2010-to-2019>.
5. Escobedo LE, Cervantes L, Havranek E. Barriers in healthcare for Latinx patients with limited English proficiency—a narrative review. *J Gen Intern Med* 2023;38:1264–71.
6. Beck TL, Le TK, Henry-Okafor Q, Shah MK. Medical care for undocumented immigrants: national and international issues. *Physician Assist Clin* 2019;4:33–45.

doi: 10.3122/jabfm.2023.230210R0

This is the Ahead of Print version of the article.