RIGID QUOTAS FOR CLINICAL TRIAL PARTICIPATION ARE THE WRONG APPROACH FOR PATIENTS OF COLOR.

The biopharmaceutical industry believes that increasing diverse enrollment in clinical trials is a critical step for increasing access to medicines and improving health outcomes. The demographics of a clinical trial should, to the extent possible, reflect the intended treatment population. **Biopharmaceutical companies are committed to leading private sector efforts and partnering with all stakeholders** to make progress in this area. Despite these efforts, there are persistent challenges and certain groups continue to be underrepresented in clinical trials.

Systemic barriers to clinical trial participation, including longstanding patient mistrust, are well documented and cannot be solved overnight or by one entity alone, or by imposing quota mandates. The public and private sectors must work together to overcome these barriers through collaboration, community partnership, and continued prioritization.

The federal government should not impose rigid quota mandates on clinical trials.

- **Mandates do not solve underlying barriers to entry into clinical trials for patients and could exacerbate the problem.** Systemic barriers exist, such as limited awareness and understanding of clinical trials; limited access to trial sites in underrepresented communities; limited **diverse investigators and staff** who can serve as community ambassadors for clinical trials; a **lack of robust data** on disease incidence in underserved communities; and the **financial and time burden** that trials can place on patients. These are all examples of the complex systemic barriers that hinder enrollment of people from underrepresented communities in clinical trials.

  A mandate would merely put the focus on meeting a target and **pull resources away from the critical and long-term effort of overcoming these systemic barriers**.

- **Requiring participation may exacerbate longstanding mistrust.** Past wrongs, including the U.S. Public Health Service Syphilis Study at Tuskegee (1932-1972), and current lived experiences with institutions of power and the health care system, make many patients weary or afraid to participate in clinical trials. When asked in focus groups and surveys, patients from underrepresented communities often express wariness about being used as "guinea pigs." A mandate reinforces this narrative, suggesting to patients that they are "just a number" to meet.

- **Mandates may hinder the very scientific progress that could bring more personalized treatments to patients in need.** A one-size-fits-all mandate approach does not take into account the unique scientific challenges of individual diseases. The mandate may lead to **unfeasibly large studies, delaying access** to medicines for all patients as studies are drawn out – potentially for years – to meet unrealistic requirements or nebulous enrollment targets that are not based on science. Mandates would also **disincentivize investments** in highly risky therapeutic areas.

Additional Reading

- *Enhancing clinical trial diversity (Insights Report Following Stakeholder Workshop)*
- *2021 Perceptions and Insights Study (CISCRP)*

Instead of imposing numbers-driven mandates, PhRMA urges policymakers to:

- Work with industry, FDA, patients and health care providers to advance a robust and equitable community-based clinical research infrastructure that would improve clinical trial accessibility and reduce barriers to clinical trial participation.
- Help advance patient-centric approaches to clinical trial design that would allow a better scientific understanding of meaningful variability in response to medicines.
- Support patient-centric approaches that can help improve the availability and quality of data that is representative of the population(s) most likely to use a given medicine.

PhRMA welcomes the opportunity to work with offices on any legislative proposals to advance diversity in clinical trials.

Recent Legislative and Regulatory Action.

FDA is making important progress to address barriers to participation, which Congress can ensure is realized by **reauthorizing PDUFA VII**. PDUFA VII seeks to advance greater use of **digital health** technologies and remote or **decentralized clinical trials** that can help increase trial access and enhance diverse participation. PDUFA VII also builds on ongoing PDUFA VI and 21st Century Cures Act activities to further advance the use and regulatory acceptance of **real-world evidence** (RWE), which can provide information about use of the medicines in patient populations beyond those included in the clinical trial.

Section 210 of the Consolidated Appropriations Act, 2021 (Public Law 116-260) requires **state Medicaid** programs, beginning on January 1, 2022 in most cases, **to cover routine patient costs** associated with participation in qualifying clinical trials (similar to what Medicare already requires).

In November 2020, the **FDA issued final guidance to enhance diversity of clinical trials** and encourage inclusivity in medical product development. This guidance offers recommendations on how product sponsors can improve clinical trial diversity by accounting for logistical and other participant-related factors that could limit participation.

And in 2018, the FDA updated its guidance to institutional review boards (IRBs) and clinical investigators regarding the **permissibility of reimbursements to patients** in clinical trials for lodging and travel, including the importance of ensuring that any payment is appropriate and does not impact the subjects' voluntary informed consent.

Congress should promote private-sector led, science-driven strategies.

Successful, long-term private sector strategies are being prospectively planned and designed into medical product development programs. These programs promote inclusion of diverse populations in clinical trials with an aim to understand the disease patterns and needs of those who are affected by the disease or condition being investigated.

PhRMA is leading the conversation.

Over the past 18 months, PhRMA has convened thousands of stakeholders as we have worked to explore a new proposed industry collaboration with diverse communities, health systems and academia that seeks to show proof of concept for a network of connected, community-rooted trial sites. Our focus is on working together to address systemic barriers, without rigid mandates or quotas in participation requirements, so that those who want to participate, can.

With **strong support from our biopharmaceutical company members**, this effort seeks to create a sustainable, community-based infrastructure focused on clinical trial diversity that increases access and addresses systemic barriers to participation, and that addresses deeply rooted mistrust that can keep some from participating in clinical trials. The effort builds off principles on enhancing clinical trial diversity that our member companies voluntarily developed and adopted in the fall of 2020.

Learn more about The PhRMA Equity Initiative and follow our progress at PhRMA.org/equity

Read More Below

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