2014 Congressional Black Caucus Fall Health Braintrust
Achieving Health Equity: *Moving From Goal to Reality*

Racial/ethnic Diversity in Clinical Trials: Implications for Black Women's Health

Laurén A. Doamekpor, Ph.D., M.P.H
National Center for Health Research
Cancer Prevention and Treatment Fund
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CONTEXT

- People of color and women have been historically underrepresented in clinical trials in the U.S.
- Federal law requires DHHS to include people of color in research studies
- African Americans represent 13% of the U.S. population but only 5% of clinical trial participants – in some studies not enough patients to know if a product is safe or effective
- This is urgent because the health of millions is at stake

WHY IS THE FDA IMPORTANT?

- Federal law require DHHS to include POC in research studies

- **BUT** -- FDA is only health agency that is exempted from these federal requirements
  - Rationale: Studies submitted to FDA for approval are conducted and paid for by private companies NOT taxpayers

- **BUT** -- FDA is responsible for ensuring the safety of packaged foods and the safety and effectiveness of medical products that touch each one of our lives.

WHY IS RACIAL/ETHNIC DIVERSITY IN CLINICAL TRIALS IMPORTANT?

- Not about political correctness
- Our understanding of disease biology is enhanced by analyzing the impact of race and ethnicity -- as imperfect as these categories are
- Genetic variance based on different ancestry does exist and does play a role in health.
- Percentage isn’t as important as having each group analyzed separately for safety and effectiveness

IMPLICATIONS FOR BLACK WOMEN'S HEALTH

- Insufficient diversity in clinical trials reduces generalizability
- Unknown and potentially inequitable distribution of risks and benefits to Black women
- Limits potential to discover effects that may be relevant to Black women

IMPLICATIONS FOR BLACK WOMEN'S HEALTH

- Results in health disparities because treatments have not been tested to be efficacious or safe for Black women

- Eventually leads to disparities in health and mortality for various diseases

IMPLICATIONS FOR BLACK WOMEN'S HEALTH

Female Breast Cancer Incidence and Death Rates per year per 100,000 women		
Racial/Ethnic Group	**Incidence**	**Death**
All	127.8	25.5
African American/Black	118.3	**33.8**
White	**132.5**	25.0

Source: National Cancer Institute - 2000-2004

IMPLICATIONS FOR BLACK WOMEN'S HEALTH – Breast Cancer

- Black women have the highest BC death rates of all racial and ethnic groups
- Black women are **3 times** more likely to die from BC but less likely to be diagnosed
- Most BC clinical trials include mostly White women
- Triple Negative BC is more common among Black women

IMPLICATIONS FOR BLACK WOMEN'S HEALTH

Cervical Cancer Incidence and Death Rates per year per 100,000 women		
Racial/Ethnic Group	**Incidence**	**Death**
All	8.7	2.6
African American/Black	11.4	**4.9**
White	8.5	2.3

Source: National Cancer Institute - 2000-2004

Examples from FDA Advisory Committee Meetings

- VBLOC Weight-loss device trial – 93% of sample was White
  - Advisory committee voted in favor of approval this year

- Sleep apnea device trial – **Zero** Black/African Americans
  - Advisory committee voted in favor of approval
  - FDA approved the device this year

FUTURE CONSIDERATIONS

- Accountability is essential
  - A change in law is NOT needed. The FDA must stop approving drugs and devices that didn't analyze and report data for major racial/ethnic groups
  - Recommendations for better diversity in post-market studies is not enough
  - Educating the public – including FDA officials and Advisors -- about importance of analyzing data by demographic groups

THANK YOU

Contact Information:

Laurén A. Doamekpor PhD, MPH
Senior Fellow
National Center for Health Research!

Cancer Prevention and Treatment Fund 1001 Connecticut Avenue, NW, Suite 1100

Washington, D.C. 20036 (T) 202-223-4000

ld@center4research.org

www.center4research.org **www.stopcancerfund.org**