

National Black Church Initiative

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The National Black Church Initiative Provides Critical Leadership In Its Meeting With The FDA Concerning African American Participation in Clinical Trials

A historic first

Washington, DC – The National Black Church Initiative (NBCI), a faith-based coalition of 34,000 churches comprised of 15 denominations and 15.7 million African Americans, initiated the first high-level scientific meeting with the Food and Drug Administration officials, on the issue of the participation of African Americans in clinical trials. This marks the first time that the Black church has utilized its enormous power and influence in the area of clinical trials.

NBCI, five years ago, unveiled a comprehensive clinical trial initiative with the goal of increasing African American participation in clinical trials by 30% entitled, Clinical Trial Education Awareness and Participation Program (CTEAPP).

Rev. Anthony Evans President of the National Black Church Initiative says, “When we first sent our letter to Commissioner Gottlieb of the FDA, we expected to be outrightly rejected. But, he accepted our invitation to meet only to decide later, after the submission of our 125-page complaint and recommendations, to back out of a Commissioner level meeting. Then the FDA tried to send us to the NIH Office of Minority Health, who does not have any regulatory authority and lack sufficient staff and budget to adequately represent the health concerns of African Americans in this country. We rejected that idea and threatened to march 30,000 African Americans in front of the FDA in downtown DC unless a meeting on clinical trials took place at the highest possible level. Of course, after that they relented.”

“Earlier during that year, we reached out to pharma and Director Francis Collins, of the National Institutes of Health. They both outrightly rejected our overtures for a partnership. They never responded to three written requests just to meet around the issue of clinical trials. As one can see, this has turned into a David and Goliath story. Since 1776 this country has never adequately addressed African American health concerns. It was only in 1985 that this country ever had an official government report on the health of African Americans under the then secretary of Health, Education and Welfare, Margaret Heckler. Both the pharmaceutical companies and the government have consistently resisted any attempt to improve African American health, then and now. Recently we tried working with Bristol Myers-Squibb over the last two and half years and after ten face-to-face meetings and repeated promises, nothing happened. This underscores NBCI's insistence of utilizing its broad moral authority to force the discussions around African American health outcomes and the value of clinical trials over the next five years.”

Our efforts have been centered around NBCI's Health Emergency Declaration (HED) which is one of the most effective faith-based health models in the country, utilizing the Black Church as a health educator. The National Black Church Initiative has been around for some twenty-five years now and is building a healthcare structure in the Black church that will last for at least one hundred years to come; impacting every major demographic group in the African American community.

After over twenty years of mastering health education in the Black Church and screenings, five years ago it became apparent to NBCI and to many researchers around the country, that African American health cannot move forward unless we participate at a 30% level into clinical trials. This means that we know how to achieve parity in health statistics with the white community's outcomes simply by including African Americans in every major clinical trial in this country. Currently the participation rate of African Americans in clinical trials, over the last 30 years, hovers between 1 and 5% depending on the study.

Access to care, critical science-based health education, clinical trials and healthy lifestyles, are the panacea of excellent health outcomes in African Americans. These are also the four pillars of NBCI's HED program.

There are no mysteries as to why we have bad health outcomes, and it is not our fault. The black community continues to pay for the mistakes of both the government and the pharmaceutical companies. Even within the minefield of the current opioid crisis NBCI still has hope for African Americans in clinical trials

The reason why African Americans do not participate in clinical trials is due to a dark history of racist medical practices and experiments on them. Harriet A. Washington, in her book *Medical Apartheid: The Dark History of Medical Experimentation on Black Americans from Colonial Times to the Present*, brilliantly underscores those reasons and the history behind them. The three entities that undermine African American participation in clinical trials are:

- 1) the lack of friendly, safe and enforceable policies and regulations by the Food and Drug Administration to compel pharma to provide the necessary resources to include African Americans in clinical trials
- 2) The U.S. pharmaceutical companies' lack of commitment to provide leadership in this area and resources (*they will say that they are doing it, so we ask the question, why has the rate of 1-5% African American participation persisted over the past 30 years?*) and
- 3) The cultural incompetency and health racism practiced by major health institutions such as Dana Farber Cancer Center in Massachusetts

We must stop all of the empty rhetoric around clinical trials and implement a policy of compassion and participation.

Given the fact that we cannot change history, the National Black Church Initiative have sought to create an initiative that will increase African American participation as well as provide critical safeguards for African Americans so that they will never be experimented on again.

NBCI is doing something extraordinary here:

- 1) It is wearing through the dark history of clinical trials
- 2) Creating an environment for African Americans to consider clinical trials as a viable option for future treatment
- 3) Using its enormous moral and political authority to negotiate and engage with the present health systems, pharmaceutical and government communities on behalf of its members which constitutes 150,000 faith communities across the country

NBCI should be applauded for such tremendous vision and efforts going forward. Meeting with the FDA is only the first of a seven-step initiative.

On February 7th the National Black Church Initiative met in what will be considered as a first round of discussions with members of the Food and Drug Administration. The Honorable Commissioner Scott Gottlieb's Office organized the discussion. The National Black Church Initiative invited the National Medical Association but they declined to participate. NBCI was represented by Rev. Anthony Evans and two qualified African American physicians.

The FDA was represented from the Office of the Commissioner by RADM Denise Hinton, Acting Chief Scientist, CAPT Richardae Araojo, Associate Commissioner for Minority Health, Dr. Milena Lolic, Lead Medical Officer, Professional Affairs and Stakeholder Engagement from the Center for Drug Evaluation and Research, Kathryn O'Callaghan, Assistant Director for Strategic Programs from the Center for Devices and Radiological Health, Jarilyn Dupont, J.D., Director of Regulatory Policy, Office of Policy, Lauren Roth, Senior Advisor to the Chief of Staff, Kathleen Quinn, Senior Advisor to the Chief of Staff, Nina Devlin, Senior Advisor, and Teresa Rubio, Health Programs Coordinator, from the Office of Health and Constituent Affairs and the Office of the Commissioner.

The discussion of the meeting centered around NBCI's six recommendations on how best to improve clinical trials. The recommendations were based on NBCI's two and a half years of research and focus groups. NBCI submitted to the FDA for the purpose of this discussion, a 125-page paper entitled, *Recommendations to the Food and Drug Administration from the National Black Church Initiative*.

NBCI, over the next five years will build a coalition of like-minded individuals, and one million stakeholders who will eventually move our government into creating more friendly and safe policies around the issue of clinical trials and compel pharma to provide the necessary resources to make a 30% participation rate a reality.

ABOUT NBCI

The National Black Church Initiative (NBCI) is a coalition of 34,000 African American and Latino Churches working to eradicate racial disparities in healthcare, technology, education, housing, and the environment. NBCI's mission is to provide critical wellness information to all of its members, congregants, Churches and the public. Our methodology is utilizing faith and sound health science.

NBCI's purpose is to partner with major organizations and officials whose main mission is to reduce racial disparities in the variety of areas cited above. NBCI offers faith-based, out-of-the-box and cutting edge solutions to stubborn economic and social issues. NBCI's programs are governed by credible statistical analysis, science based strategies and techniques, and methods that work. Visit our website at www.naltBlackChurch.com.

