

Good afternoon and thank you for joining the US Food and Drug Administration webinar event. If you have questions during the presentation, we would like to encourage you to type them on the chat box on your screen. It will be time at the end of the webinar for the presenter to answer some of your questions. Please stand by and we will begin in a few minutes.

Today's webinar on steps to addressing health disparities is sponsored by FDA's office of minority health. The office of minority health advances of these regulatory mission and addressing the reduction of racial and ethnic health disparities and in achieving the highest standard of health for all. The office provides leadership and direction in identifying policy and actions that may help reduce health disparities including the coordination of efforts across the agency

At this time, I'd like to introduce our presenter. Dr. Michelle Yeboah is the acting director of the FDA's office of minority health. Today's presenter will discuss how the agency was addressing minority health and health disparities within a regulatory science context. There will be time at the end of the webinar for questions. Slides from the presentation are available at [www.fda.gov/fdabasics](http://www.fda.gov/fdabasics)

An archived version of this webinar will be available from the same address. I would like to turn to our presenter who will begin the presentation. Michelle?

Good afternoon, and thank you so much for joining us today at our FDA office of minority health webinar. My name is Dr. Michelle Yeboah, I am the acting director of the office of minority health. I'm going to begin with an overview of the office of minority health and also an overview of the FDA. I am also going to talk about the history of the FDA office of minority health as well as Office of Minority Health key initiatives and saving some time at the end for some questions and answers.

Some background about the FDA, the FDA is charged with protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, the food supply, biological products, medical devices, cosmetics, radiation emitting products and by regulating tobacco. Specifically, FDA is responsible for advancing the public health by helping to speed innovations that make medicines and foods safer and more effective, provided the public with accurate science based information, regulated the manufacture of marketing and distribution of tobacco products to protect the public health and reduce use by minors, and by addressing the nation's counterterrorism capability and ensuring the security of the supply of foods and medical products.

To give you some history of the office of minority health the patient protection and affordable care act section 10334 was signed into law on March 23. That established our office of minority health. In addition to that, this act also mandated the establishment of six new offices of minority health within the Department of Health and Human Services. Among these six is of course our office of minority health at the Food and Drug

Administration, the Centers for Disease Control office of minority health, HRSA, the health resources and services administration, SAMHSA, the substance abuse and mental health administration as well as AHRQ, the agency for healthcare research and quality and at CMS, the centers for Medicare and Medicaid services.

FDA has a unique role in reducing health disparities given its regulatory mandate and in essence every agency plays a critical role in working together to eliminate health disparities.

Along with this coordinated effort to reduce health disparities, the Department of Health and Human Services released its action plan to reduce health disparities. This action plan outlines goals and actions that HHS will take to reduce disparities among racial and ethnic populations. FDA works in partnership with HHS to implement this plan. In addition this plan also enhances the integration of improved coordination to eliminate health disparities. This plan is also available online.

Before I go into what our office does in specifics, I wanted to talk for a minute about what a health disparity is. A health disparity is really differences of health between groups of people. It's also persistent or frequent gaps in health or differences in treatment among groups of people and these differences can often affect how frequently a disease affects a group.

So in addition health disparities is not a new phenomena. Health disparities have been talked about for years and years.

In the 1800s, W.E. Dubois talked about health disparities. In 2003 The Institute of medicine released the unequal treatment report. This report highlighted the importance of addressing health disparities and it also documents poor health outcomes among racial and ethnic relations. This report found that across virtually every therapeutic intervention ranging from high-technology procedures to the most elementary forms of diagnostic and treatment interventions, racial and ethnic populations received fewer procedures and poorer quality of medical care. It should also be noted that there are multiple overlapping lenses to look through when you're talking about health disparities. They can occur by disease, cancer, HIV and others, by population, racial and ethnic, gender or age, by risk factor in terms of diet or vaccination status, or by geography in terms of urban versus rural, but for our office, we are really looking at racial and ethnic and disparities.

I should mention that FDA's office of minority health is in line with FDA strategic priorities for 2011 to 2015. In section 2.4, one of the strategic priorities is to expand efforts to meet the needs of special populations. In addition, last year the agency released the advancing regulatory science in FDA report, and in this report they talked about harnessing diverse data to improve health outcomes and by strengthening social and

behavioral science, which have implications for vulnerable populations.

Now I should mention, that while FDA centers and offices have addressed health disparities for years, FDA's office of minority health serves as the principal advisor to the Commissioner on minority health and health disparities. The office provides leadership and direction in identifying agency actions that can help reduce health disparities including the coordination of efforts across the agency. The mission of the office of minority health is to advance FDA's regulatory mission by addressing the reduction of racial and ethnic health disparities and achieving the highest standard of health for all. Specifically, our goal is to strengthen FDA's capacity to address minority health and health disparities across the agency through coordinated leadership and regulatory actions and decision-making. In addition, the goal of the office is to promote effective communication and dissemination of information to the public, particularly underserved populations. As we all know, we have many outlets for getting information but it goes beyond the Wall Street Journal, The Washington Post, etc. So our goal is really to expand how we deliver information to some of the most vulnerable populations. In addition to that, our last goal is to strengthen the evaluation of subpopulation with race and ethnicity.

The FDA office of minority health currently has a few health disparities priority areas. They include diabetes, obesity, HIV and AIDS, tobacco, and aging.

And some of our current initiatives, one in particular is FDA's enhancing diversity on scientific advisory committees. And when we say advisory committees I know some of you who are a part of this webinar know this already but our advisory committees and panels, they serve as independent experts that provide advice on scientific policy and technical related matters.

One of the things this office is charged with is assisting in the recruitment and tracking of qualified potential candidates left practice or research experience with underserved populations and so we're looking to enhance our advisory committees. In addition to that we were also recruiting through outreach to academic institutions, health professional groups, advocacy organizations and scientific groups so we encourage you all to visit our website to learn more about this.

In addition some of our initiatives include stakeholder partnerships at academic, research collaboration, advocacy organizations, health professionals and with industry. One of the things that we are trying to do is really to advance how we view regulatory science and making sure that we are hitting various stakeholders that can help us to learn about health disparities and regulatory science and in essence, looking to enhance how we look at health disparities and the safety and efficacy of FDA regulatory products, to make sure that we answer and ask some of those critical questions in terms of what is its real life application to the public.

Last year we had a fantastic conference that gathered industry, academia health professional groups, nonprofits and several various entities and this conference was really

the dialogs on diversity in clinical trials research that occurred in September 2011. The overarching conference goals were to increase the participation of underrepresented and underserved populations in clinic research but also to share successful and innovative practices and recruitment retention and analysis of women and minorities in clinical trial research.

Proceedings of this conference can be found at the end of your slide where we have some slides as well as some videos about the conference.

More recently, during national minority health month, the office of minority health held an FDA lectureship. And this lectureship was really tailored towards promoting internal FDA discourse on the intersection of regulatory science and health disparities research

In addition we also have a new FDA office of minority health webpage which can be found on your slide below. There is a link. We encourage all to take a look at our webpage to learn about some more about our current initiatives and also to leave any questions or comments that you would have for us.

## Q&A

Thank you. This concludes the presentation portion of the webinar. If you have not already entered your questions, please do so at this time so that we may review them. If you already submitted a question there is no need to reenter it. As we prepare to begin answering some of your questions, we would like to let you know that in an archived version of this presentation will soon be available via the FDA website. A copy of the presentation slides is available now.

One question I received was, what is FDA doing about inclusion and accountability within industry? I should mention that our FDA dialogues on diversity and clinical trials included representatives from academia, research, and advocacy groups, industries, and various federal federal agencies. This conference is tailored toward talking about the best practices. Many -- and clinical trials, this conference was really focused on successful and innovative practices and with over 200 participants it was deemed a success.

One question received is, what are you doing with organizations with whom you have formed partnerships? One such example in terms of our collaborations are working with the University of Hawaii, the Department of pharmacy as well as the University of Hawaii Manoa in terms of their office of public health and science. What we are trying to do within our office is to make sure that we are also taking care of the next generation of researchers who can further advance our FDA knowledge as it relates to health disparities and regulatory science, or the science of making sure that the safety and efficacy of FDA regulatory is made. So we are partnering with various entities that also looking at other universities to look at how we can advance to to education is to -- and also trying to partner with faculty as it relates to increasing the regulatory science pathways among their students and themselves as well. On our radar is also competing with joint meetings

of research entities within academic societies as well as health professional groups.

At this time, our speaker would take the final question.

One of the questions received is kind of how it is FDA's office of minority health -- how do we do what we do? In essence as I mentioned, there are six new offices of minority health and we also have the new institute. One of the differences between our office of minority health and all the other agencies is that we are not a service-based entity and from the time you go to sleep until the time you wake up, FDA touches you. With that being said, we're looking at how we communicate and communicate to the public before they occur. In addition to that we are also interested in making sure that we are looking at a racial and ethnic subpopulation data analysis and making sure we're asking some of the critical questions in terms of how FDA's regulatory decision-making impacts vulnerable populations.

There is also an opportunity to post your questions to the FDA basics website if you have some additional questions, and I also want to mention that issues such as personalized medicine and granular analysis of diverse data sets are also areas in which the office of minority health is looking at in addition to risk communication and making sure that as we move forward in our regulatory decision-making that we are taking into account its implications on vulnerable populations, specifically as it relates to us to minorities.

The US food and drug appreciates your participation and we hope you will participate again in the future. This concludes our webinar session.