



U.S. FOOD AND DRUG ADMINISTRATION OFFICE OF MINORITY HEALTH



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Overview

- Background-FDA
- History of FDA Office of Minority Health (OMH)
- OMH Key Initiatives
- Questions and Answers



Background

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.



Background

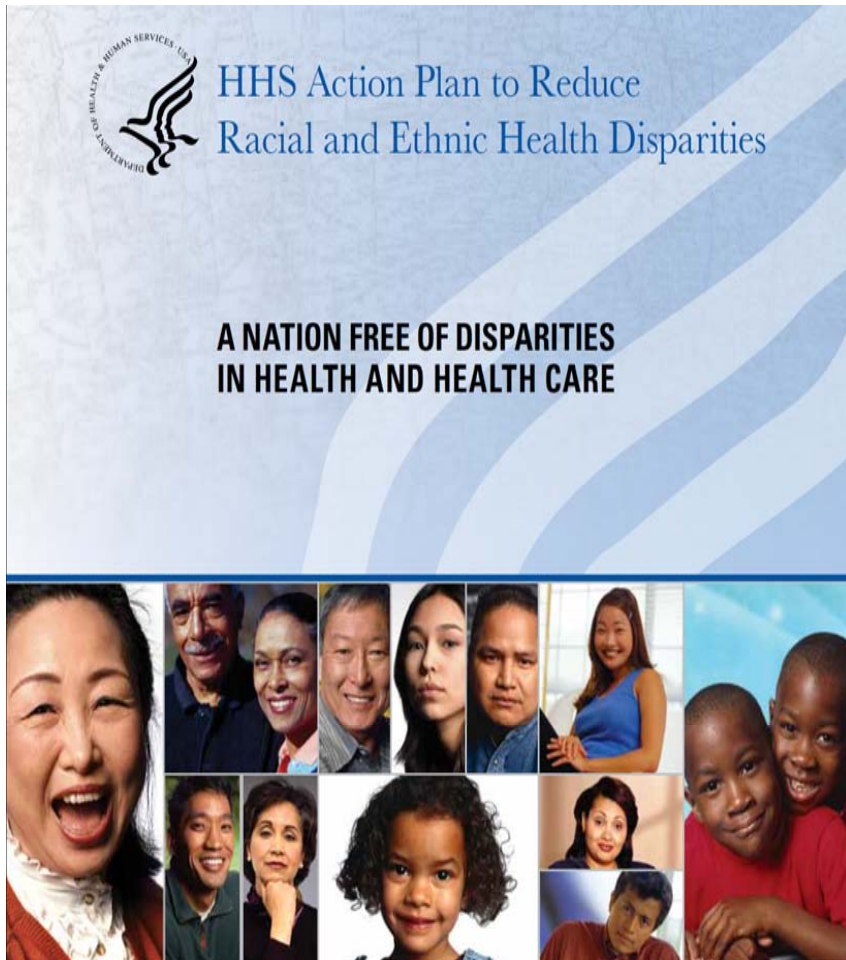
Specifically, FDA is responsible for advancing the public health by:

- **Helping** to speed innovations that make medicines and foods safer and more effective;
- **Providing** the public with the accurate, science-based information they need to use medicines and foods to improve their health;
- **Regulating** the manufacture, marketing, and distribution of tobacco products to protect the public and reduce tobacco use by minors;
- **Addressing** the Nation's counterterrorism capability and ensuring the security of the supply of foods and medical products.

History of the Office of Minority Health

- The Patient Protection and Affordable Care Act Section 10334-March 23, 2010
- Mandates the establishment of six new Offices of Minority Health within the Department of Health and Human Services (HHS) - among these six is the Office Of Minority Health at the Food and Drug Administration- (CDC, HRSA, SAMHSA, AHRQ, CMS)

HHS Action Plan To Reduce Disparities

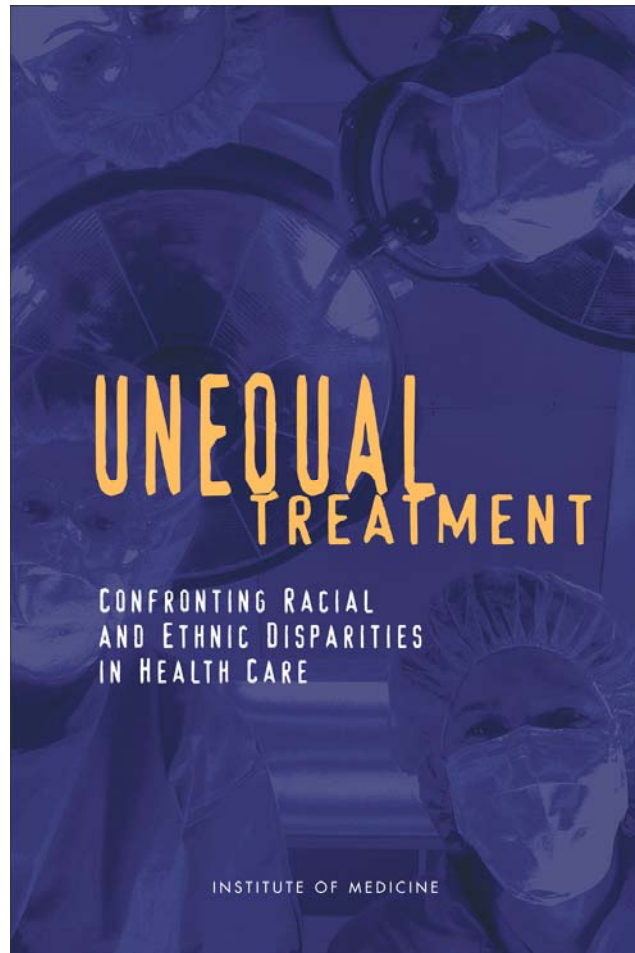


- HHS Action Plan to Reduce Racial and Ethnic Health Disparities
- Outlines goals and actions that HHS will take to reduce health disparities among racial and ethnic populations.
- FDA OMH works in partnership with HHS to implement this plan.

What is a “Health Disparity”?

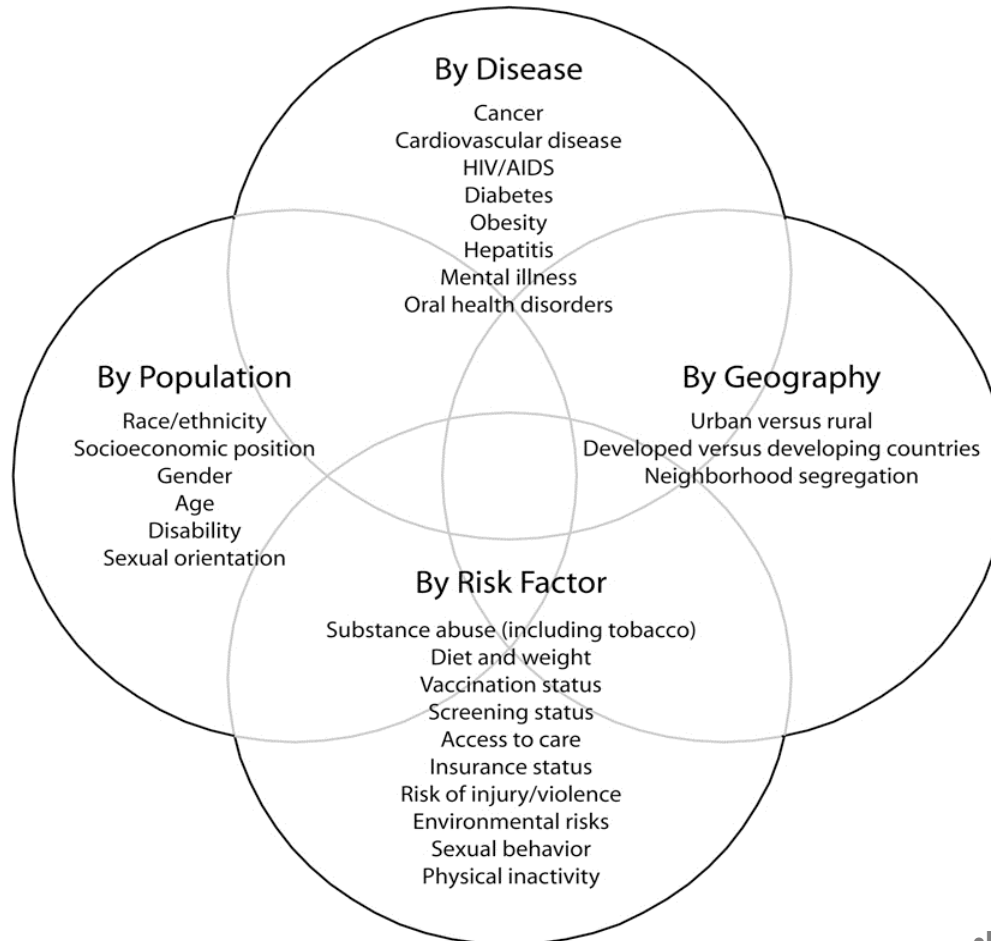
- Differences in health between groups of people
- Persistent or frequent gaps in health
- Differences in treatment among groups of people
- These differences can affect how frequently a disease affects a group
- How many people get sick and
- Can affect how often the disease causes death

Health Disparities in the U.S.



Found that across many therapeutic interventions racial and ethnic populations received fewer procedures and poorer quality medical care

Multiple and Overlapping Lenses for Viewing Health Disparities



FDA Strategic Priorities & Plans

- **FDA's Strategic Priorities 2011-2015**
- 2.4 Expand Efforts to Meet the Needs of Special Populations
- **Advancing Regulatory Science at FDA**
- Harness Diverse Data to Improve Health outcomes
- Strengthen social and behavioral science





FDA OMH

- 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



FDA OMH Mission

The Office of Minority Health advances FDA's regulatory mission in:

- Addressing the reduction of racial and ethnic health disparities and
- Achieving the highest standard of health for all

FDA OMH

Goals

- Strengthening FDA capacity to address minority health and health disparities across the Agency through coordinated leadership on regulatory actions and decision making
- Promoting effective communication and the dissemination of information to the public, particularly underserved, vulnerable populations.
- Strengthening the research and the evaluation of sub-population data associations with race and ethnicity.



FDA OMH

Health Disparities Current Priority Areas

- Diabetes
- Obesity
- HIV/AIDS
- Tobacco
- Aging



FDA OMH Current Initiatives

Enhancing Diversity on FDA Scientific Advisory Committees

- Recruitment and tracking of qualified potential candidates who have practice or research experience with underserved populations
- Recruitment through outreach to academic, health professional, advocacy and scientific groups.



FDA OMH Initiatives

Stakeholder Partnerships

- Academic
- Research
- Collaboration
- Advocacy Organizations
- Health Professional
- Industry



FDA OMH Current Initiatives

Dialogues on Diversity in Clinical Trials Research Conference (Sept. 2011)

Overarching Conference Goals:

- Increase the participation of under-represented and underserved populations in clinical trial research.
- Share successful and innovative practices in recruitment, retention and analysis of women and minorities in clinical trials research.



FDA OMH Current Initiatives

FDA Lectureship

- Commissioner's Health Disparities Lectureship Series
- Primary goal to promote internal FDA discourse on the intersection of regulatory science and health disparities research



FDA OMH Current Initiatives

Communications

- Creation of FDA OMH Webpage
- <http://www.fda.gov/MinorityHealth>



Q & A



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