FDA Update: Minority Health and Stakeholder Engagement

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10th Annual National Summit on Health Disparities
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Agenda

FDA Office of Minority Health
- History and Goals of FDA Office of Minority Health
- Current Activities

FDA Office of Health and Constituent Affairs (OHCA)
- What We Do and When
- Patient Network
- Cardiovascular and Endocrine Liaison Program
Historical Overview

- **1985** - HHS Secretary Margaret Heckler released the Secretary's Task Force on Black and Minority Health Report
- **1990**—The Office of Research on Minority Health (ORMH) was established by the NIH Director.
- **1997**- the President Clinton’s Initiative on Race was established with the goal to eliminate racial/ethnic disparities in health by the year 2010.
- **2002** - Institute of Medicine (IOM) released the landmark report, Unequal Treatment: *Confronting Racial/Ethnic Disparities in Health Care*
- **March 2010 Affordable Care Act- Section 10334 mandated creation of OMH across all HHS divisions**: also advanced NIH- Office-Center to an Institute (NIMHD); steps begun to establish FDA OMH
- **April 2011**, the U.S. Department of Health and Human Services (HHS) released an Action Plan to Reduce Racial and Ethnic Health Disparities, which outlines goals and actions HHS will take to reduce health disparities among racial and ethnic minorities
“Translating Research Evidence Into Practice to Reduce Health Disparities: A Social Determinants Approach”

By Disease
- Cancer
- Cardiovascular disease
- HIV/AIDS
- Diabetes
- Obesity
- Hepatitis
- Mental illness
- Oral health disorders

By Population
- Race/ethnicity
- Socioeconomic position
- Gender
- Age
- Disability
- Sexual orientation

By Geography
- Urban versus rural
- Developed versus developing countries
- Neighborhood segregation

By Risk Factor
- Substance abuse (including tobacco)
- Diet and weight
- Vaccination status
- Screening status
- Access to care
- Insurance status
- Risk of injury/violence
- Environmental risks
- Sexual behavior
- Physical inactivity

FDA Office of Minority Health

Mission
The Office of Minority Health advances FDA’s regulatory mission in addressing the reduction of racial and ethnic health disparities and in achieving the highest standard of health for all.

- Goal 1- To improve and strengthen regulatory science informing the research and evaluation of sub-population data associations with race and ethnicity.

- Goal 2- To strengthen FDA capacity to address minority health and health disparities across the Agency

- Goal 3- To promote effective communication and the dissemination of information to the public, particularly underserved, vulnerable populations.
Overview of Current Collaborations Program

- **Academic and Other Stakeholder Collaborations under FDA MOU’s**
  - Univ of Hawaii, Meharry, Univ of Nebraska

- **HHS Partners**
  - Interagency Agreements
    - National Institutes for Minority Health and Health Disparities (NIMHD)
    - National Human Genome Research Institute (NHGRI)

- **Inter Center agreements**
  - NCTR
  - ORA
  - CBER
  - CDER

- **Cooperative Agreements**
  - FDA Centers for Excellence in Regulatory Science and Innovation
    - University of Maryland & Georgetown University
  - National Alliance for Hispanic Health- “Genes, Culture, and Health Program” – enhance understanding of the role of genetics in health and Health decision making for Hispanic communities
FDA Safety and Innovation Act of 2012

- **Section 907** - Reporting of Inclusion of Demographic Subgroups in Clinical Trials and Data Analysis in Applications for Drugs, Biologics, and Devices
  - Requires a report by **July 9, 2013**
    - Extent of subgroups in applications, in FDA reviews for safety and efficacy; if information is publically available on FDA website or in labeling
  - Requires an Action Plan by July 9, 2014

- **Section 1137** - Requires FDA to develop and implement strategies to solicit the views of patients during the medical product development process and consider the perspectives of patients during regulatory discussions by
  - Fostering participation of a patient representative who may serve as a special government employee in appropriate agency meetings with medical product sponsors and investigators; and
  - Exploring means to provide for identification of patient representatives who do not have any, or have minimal, financial interests in the medical products industry.

- **Section 1138** - Ensuring Adequate Information Regarding Pharmaceuticals for All Populations, Particularly Underrepresented Subpopulations, Including Racial Subgroups
  - Requires that FDA post on website a communication plan by **July 9, 2013** to inform and educate health care providers and patients on the benefits and risks of medical products, with particular focus on underrepresented populations including racial subgroups
Minority Health

The FDA has resources to help minority communities safely use the medicines, foods, and other products the Agency regulates. Whether you are a patient, a student, health professional or caregiver, this website has resources to help you stay informed and stay healthy.

FDA Minority Health Publications

- FDA en Español
- General Health Information
- Resources for Health Professionals
- Translated FDA Materials

Special Health Issues

- The Facts about Diabetes
- High Blood Pressure—Medicines to Help You
- HIV and AIDS Related Therapies
- Vitamins and Herbal Supplements: What You Need to Know
- Medicines: A Guide for Older Adults

In the Spotlight...

- APRIL is National Minority Health Month
- Productos de tabaco
- Eat for a Healthy Heart
- What is a Home-use HIV Test Kit?
- Know Your Online Pharmacy

Recalls & Alerts

- Reporting Problems to FDA (video)
- MedWatch—Safety Alerts
- Codeine use in Children: Safety Review
- Alert for Green Day Brand Dried Coconut
- Temporary Tattoos, Henna/Mehndi, and “Black Henna”

About Us

- FDA’s Office of Minority Health
- Current Initiatives
- FDA Fellowship, Internship, Graduate Opportunities
- OMH Blog posts
- Webinar: Steps to Address
FDA Office of Health and Constituent Affairs
(formerly Office of Special Health Issues)
WHAT WE DO

- Advises the Commissioner and other key FDA officials on matters related to patients, patient advocacy, health professionals, consumers, state and federal activities and industry issues.

- Assists in the planning, administration, development, and evaluation of FDA policies related to patient advocacy and health professional organizations, consumers, states, industry on serious and life-threatening issues.

- Serves as a Liaison between FDA and stakeholder organizations to educate various constituents on FDA related issues and activities. Specifically, the drug approval process, clinical trial design, and expanded access to investigational therapeutic products.
FDA Office of Health and Constituent Affairs
(formerly Office of Special Health Issues)
WHAT WE DO........

• Coordinates and implements policies, programs, and initiatives related to MedWatch including the MedWatch web pages, E-list, RSS feed, and Twitter account.

• Administers MedWatch, the FDA safety information and adverse event reporting program. Assures that patient perspectives are taken into consideration during drug development and policy issues through the patient representative and patient consultant programs.

• Provides internal coordination on FDA activities related to patient advocacy, health professional organizations, consumer groups, state organizations and industry groups on high-priority topics such as serious and life-threatening diseases, imminent public health needs and other special health issues.
FDA Office of Health and Constituent Affairs IS CALLED ON WHEN...

- There is a public outcry to address an unresolved medical problem
- There is a serious, life-threatening condition or human medical product issue that presents a major public health/safety concern
- FDA Centers need support interacting with persistent patients, patient advocates, or health professionals
- Agency seeks collaboration with health professional organizations
- Congress or the Department requests action on an issue which needs input from patients, patient advocates, health professionals, or health professional organizations
- Agency disseminates broad messaging on human medical product safety issues
FDA Patient Network

- Multifaceted Website, including:
  - Ongoing FDA Initiatives
  - How Medical Products Get Approved
  - Clinical Trials Participation
  - Accessing Investigational Products using Expanded Access
  - Off-Label Use of Approved Drugs
- FDA Advisory Committees
- Educational Modules
- Interactivity (i.e. feedback mechanisms, live chats)

- Biweekly Email Newsletter (started in March 2011. To sign up, go to: https://public.govdelivery.com/accounts/USFDA/subscriber/new?topic_id=USFDA_203)

- Annual Meeting
- Listening Sessions and Other Briefings
Step 4 FDA Review

If a drug developer has evidence from its early tests and preclinical and clinical research that a drug is safe and effective for its intended use, the company can file an application to market the drug. The FDA review team thoroughly examines all submitted data on the drug and makes a decision to approve or not to approve it.

Find out how the FDA is Speeding Up the Approval Process.

New Drug Application

A New Drug Application (NDA) tells the full story of a drug. Its purpose is to demonstrate that a drug is safe and effective for its intended use in the population studied.

A drug developer must include everything about a drug—from preclinical data to Phase 3 trial data—in an NDA. Developers must include reports on all studies, data, and analyses. Along with clinical results, developers must include:

- Proposed labeling
- Safety updates
- Drug abuse information
- Patent information
- Any data from studies that may have been conducted outside the United States
- Institutional review board compliance information
- Directions for use

FDA Review
Get Involved

You can participate in FDA's important decisions about the regulation of medical products in many ways. You don't have to be an expert, and you don't need lots of time. Find out how you can make your voice heard and help ensure the effectiveness and safety of drugs, devices, and other medical products.

**Become a Patient Representative**

Add your voice to FDA processes to ensure input into important medical product development, review, and policy questions. Find out how.

**Calendar of Public Meetings**

As a member of the public, you are welcome to attend the FDA's meetings. See what's coming up that may interest you.

**Get Involved**

- Become a Patient Representative
- Calendar of Public Meetings
- Ask the FDA
- Join a Live Chat
- Listen to Webinars With FDA Experts
- Comment on FDA Regulations
- Report Side Effects on MedWatch
- Subscribe to Our E-Newsletter

**Report Side Effects on MedWatch**

Read More
FDA Office of Health and Constituent Affairs
Cardiovascular and Endocrine Liaison Program

PURPOSE:

• Serves as a liaison between FDA and the cardiovascular and endocrine health professional and patient communities

• Encourages and supports active participation in forming FDA regulatory policies advancing the safety and effectiveness of human medical products that treat diabetes, hypertension, heart disease, and obesity

• Promotes healthy dietary and nutrition practices
Cardiovascular and Endocrine Liaison Program
Engagement Tools and Activities

• Launch of FDA Cardiovascular (CV) and Endocrine web pages and CardioBeat and Diabetes Monitor e-mail subscription lists
• Presenting and attending health professional and patient advocacy conferences
• Facilitating and moderating stakeholder meetings, listening sessions and roundtables with FDA
• Communicating with and educating stakeholders utilizing OSHI’s existing communication tools (e.g. newsletters, briefings, stakeholder calls, webinars, etc.)
• Informing and educating the endocrine/cardiovascular health professional community utilizing appropriate Medscape tools
• Identifying publications for regular submission
Diabetes Information

Safe Disposal of Sharps
What do you do with used needles and other sharps?

On these pages, expect to find diabetes-related information tailored to patients with Type 1 and Type 2 diabetes, with links to FDA web pages and other trusted government web sites. FDA is committed to getting accurate, science-based information in the hands of people with diabetes so they can use foods, medicines, and devices to maintain and improve their health. With the incidence of diabetes skyrocketing, it is important to FDA that we do what we can to inform patients.

Diabetes is the seventh leading cause of death in the United States. An estimated 25.8 million people in the U.S.—approximately 8.3% of the population—have diabetes.
As a subscriber to FDA Diabetes Monitor, you will receive timely information about diabetes-related products, including product approvals, safety warnings, notices of upcoming public meetings, and notices of draft guidances.

On July 26, 2012, FDA approved Vascepa (icosapent ethyl) capsules as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe (TG greater than or equal to 500mg/dL) hypertriglyceridemia manufactured by Amarin Corp.

The product labeling will be posted soon to Drugs@FDA, on the FDA website.
Cardiovascular disease—including heart disease and stroke—is the leading cause of death in the United States. Every day, 2,200 people die from cardiovascular disease—that’s 815,000 Americans each year, or 1 in every 3 deaths.

FDA-regulated medications and devices are among the most common methods used to manage cardiovascular disease. FDA is committed to getting accurate, science-based information in the hands of people affected by cardiovascular disease so they can use medicines, devices and foods to maintain and improve their health.
Information about FDA cardiovascular-related product approvals, safety warnings, notices of upcoming public meetings, and notices about proposed regulatory guidances. Please do not reply to this message.

Cardiovascular and Renal Drugs Advisory Committee Meeting

FDA’s Cardiovascular and Renal Drugs Advisory Committee will meet September 14, 2012 from 8 a.m. to 5 p.m. at the FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD.

The committee will discuss a Novartis Pharmaceuticals NDA for imatinib mesylate as adjunctive therapy for the treatment of pulmonary arterial hypertension (WHO Diagnostic Group 1), to improve exercise capacity and cardio-pulmonary hemodynamics in patients who remain symptomatic despite treatment with two or more approved vasodilator therapies.

For more information, visit FDA's website at http://www.fda.gov/AdvisoryCommittees/Calendar/ucm313019.htm
Thank You!