





# Outline

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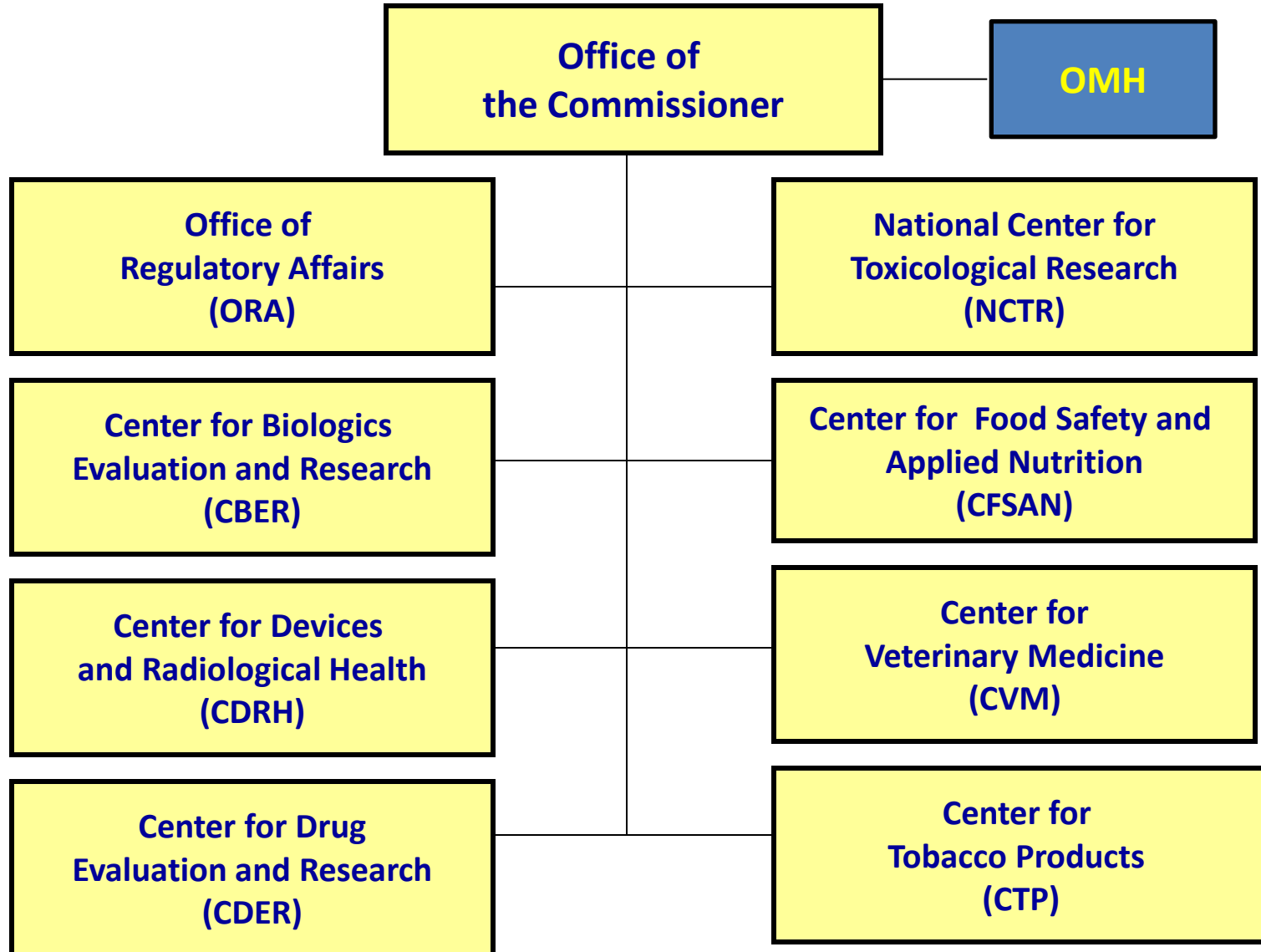
## ***What Does FDA Do?***

- FDA regulates 25% of US commerce
- Assures the safety, effectiveness and security of human and veterinary drugs, vaccines and other biological products, medical devices, our food supply, cosmetics and radiation-emitting devices
- Regulates tobacco products
- Advances Public Health
  - Helps speed innovations that make products more effective, safer and more affordable
  - Helps the public get accurate, science-based information about these products

## What does FDA *not* regulate?

- Regulate medical practice, services, or pricing
- Advertising (excluding drugs and medical devices), alcohol, consumer products (unless radiation emitting), illicit drugs, health insurance, meat and poultry, pesticides, restaurants, grocery stores, water
- FDA does *not* conduct clinical trials

# How is FDA Organized?



## FDASIA Section 907 History

- American Heart Association, WomenHeart, and Society for Women's Health Research lobbied Congress for legislation requiring FDA to publicly report data on the inclusion and analysis of women in FDA applications
- Resulting Legislation: Heart for Women's Act (HEART)
  - Sen. Debbie Stabenow (D-MI) and Rep. Lois Capps (D-CA)
- Provision added to include reporting of a race and ethnicity
  - Sen. Benjamin Cardin (D-MD)
- 2012 Final legislation reauthorizing FDA user fees (essential for Agency operations)
  - Requirements for an initial public report on inclusion data from applications
  - Subsequent action plan to address deficiencies



# Section 907 Requirements: A Report

Within one year of enactment:

- Provide to Congress
- Post on FDA website
- Report On:
  - Extent of clinical trial participation
  - Quality of analyses to determine safety and effectiveness for demographic subgroups included in applications submitted to FDA
  - Take into account FDA regulations and requirements for protection of sponsor confidential commercial information





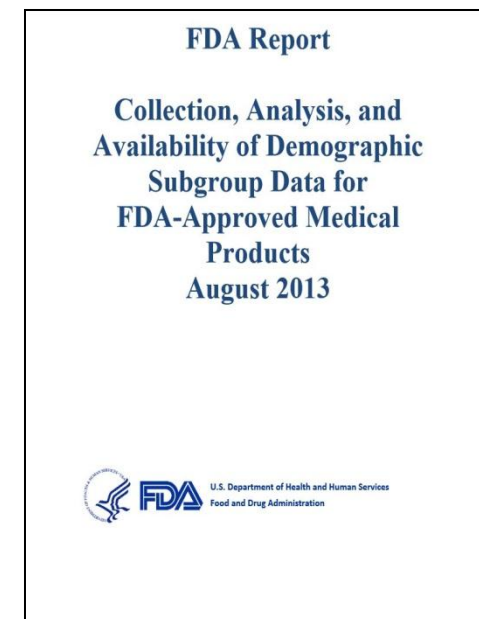
# Section 907 Requirements: An Action Plan

Not later than 1 year after the publication of the 907 report, acting through the Commissioner, FDA shall publish ***an action plan*** on the website of the Food and Drug Administration, and provide such publication to Congress.

- Recommendations to improve the completeness and quality of data analyses for demographic subgroups in:
  - Summaries of product safety and effectiveness data for drugs and devices submitted to FDA for marketing approval; and in labeling;
- Recommendations on the inclusion or lack of availability of subgroup safety data in labeling;
- Recommendations to otherwise improve the public availability of such data to patients, health care providers, and researchers;
- A determination with respect to each recommendation identified in subparagraphs (A) through (C) that distinguishes between product types referenced in subsection (a)(2)(B) insofar as the applicability of each such recommendation to each type of product.

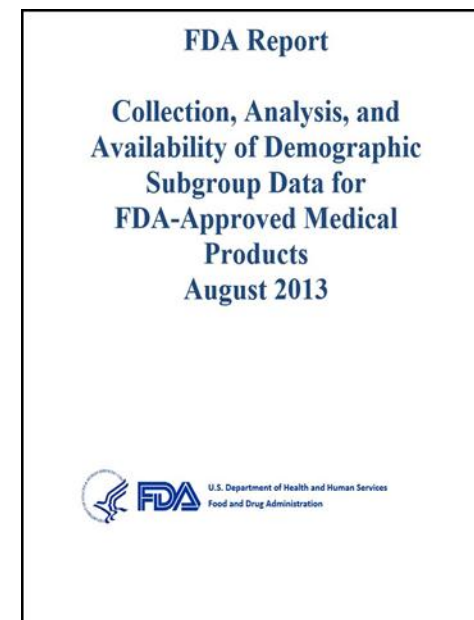
# Section 907 Report Methodology

- Reviewed approved applications from 2011
  - 72 Applications
  - 5 CBER (FDA Center for Biologics Evaluation and Research) applications, Biological Licensing Applications (BLAs)
  - 30 CDER (FDA Center for Drug Evaluation and Research) applications, New Molecular Entities (NMEs)
  - 37 CDRH (FDA Center for Devices and Radiological Health) applications, Premarket Approval Applications (PMAs)
- Pivotal studies included only
- Pulled demographic data (sex, age, race, and ethnicity) as the variables of interest



## Section 907 Report Findings

- The statutes, regulations, and policies currently in place generally give product sponsors a solid framework for providing data in their applications on the inclusion and analysis of demographic subgroups.
- In general, sponsors are describing the demographic profiles of their clinical trial participants for sex and age, and the majority of applications submitted to FDA include subset analyses.
- FDA shares this information with the public in a variety of ways.



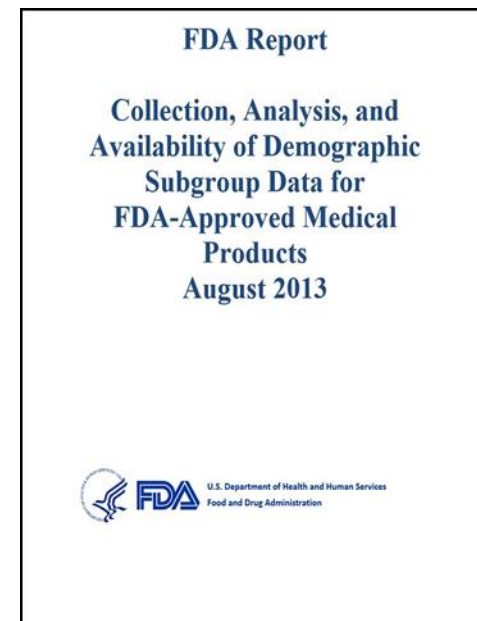
## Section 907 Report Findings Cont'd (2)

### Drugs and Biologic Products

- Participants' sex was the most consistently reported in the medical product applications
- Patients' age and sex reflected the disease studied

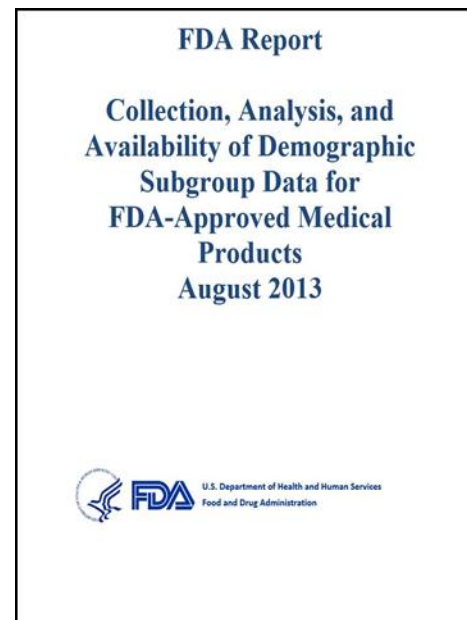
### Devices

- Patient participation by age and sex varied by product type



## Section 907 Report Findings Cont'd (3)

- Ethnicity (as defined by the Office of Management and Budget as “Hispanic or Latino” and “Not Hispanic or Latino”)\* not consistently reported in clinical studies across medical product types.
- Inclusion of subgroups did not necessarily mean that sufficient data was collected for meaningful analysis or to detect differences.



\*<http://www.fda.gov/RegulatoryInformation/Guidances/ucm126340.htm>

# Section 907 Action Plan Development

- Docket for public comment, August 20, 2013 – May 16<sup>th</sup> 2014.
- FDA Working Group
  - ✓ Office of Minority Health, Lead
  - ✓ Office of Policy and Planning
  - ✓ Office of External Affairs
  - ✓ Office of Chief Counsel
  - ✓ Centers (CBER, CDER, and CDRH)
  - ✓ Office of Women's Health
  - ✓ Office of Health and Constituent Affairs
- Public meeting, April 1, 2014
- Stakeholders meetings for additional input



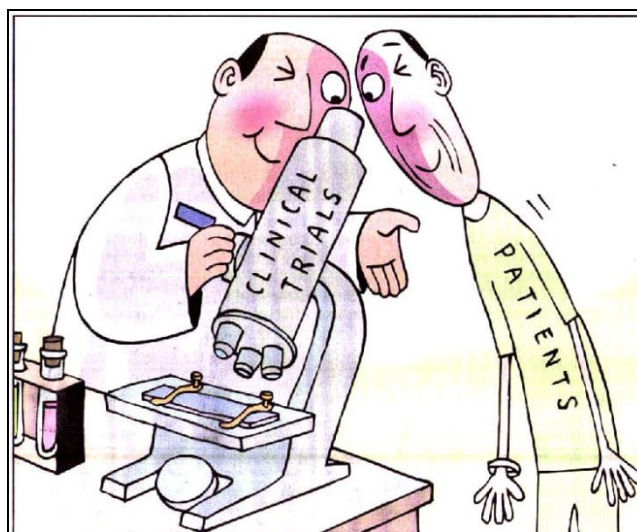
## Patient and Health Professional Groups' Concerns

- The proportion of women, minorities, and the elderly in industry-sponsored clinical trials is not consistent with the prevalence of the disease in the underlying population
- Health professionals and patients do not have sufficient demographic information to make well-informed treatment and diagnostic decisions
- Achieving racial and ethnic participation, and relevance to U.S. subgroups, can be a particular problem when foreign data is used



# Industry Concerns

- General lack of awareness about, and limited physical access to, clinical trials among some demographic subgroups
- The needs of global development result in clinical trials in geographic regions with substantially different racial and ethnic representation than the U.S.





# Congressional Concerns

April 30, 2014 Letter to FDA led by Senator Stabenow

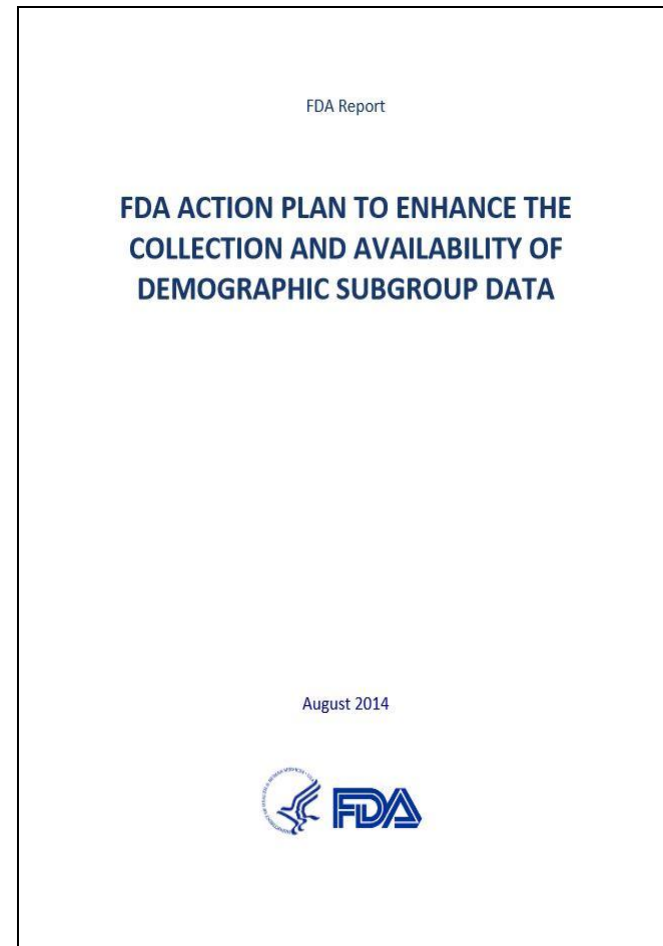
- Require representative proportions of women and minorities in industry-sponsored clinical trials comparable to NIH
- Specific actions FDA will take, in cooperation with industry:
  - ✓ to achieve meaningful subgroup analyses for safety and efficacy
  - ✓ clear timelines for enforcement that do not unnecessarily disrupt trials
  - ✓ making results transparent and publicly available
- Publicly reporting progress implementing the Action Plan:
  - ✓ regular
  - ✓ further action needed



## Section 907 Action Plan

### Three overarching priorities:

- **Priority One:** Improve the completeness and quality of demographic subgroup data collection, reporting and analysis (**Quality**)
- **Priority Two:** Identify barriers to subgroup enrollment in clinical trials and employ strategies to encourage greater participation (**Participation**)
- **Priority Three:** Make demographic subgroup data more available and transparent (**Transparency**)



## Priority One: Improve the Completeness and Quality of Demographic Subgroup Data (Quality)

- 1.1. Review and develop a work-plan for updating, and/or finalizing, relevant guidance on demographic subgroup data, including FDA staff training and outreach to external stakeholders, as needed, for implementation
- 1.2. Work with sponsors to revise medical product applications to enhance information on demographic subgroups in medical product applications
- 1.3. Strengthen FDA reviewer training by adding education/training around demographic inclusion, analysis, and communication of clinical data
- 1.4. Enhance FDA's systems for collecting, analyzing, and communicating diverse clinical information to optimize safe and effective use of medical products in diverse populations over the total product life cycle
- 1.5. Conduct research on specific areas of public health concern related to demographic subgroups



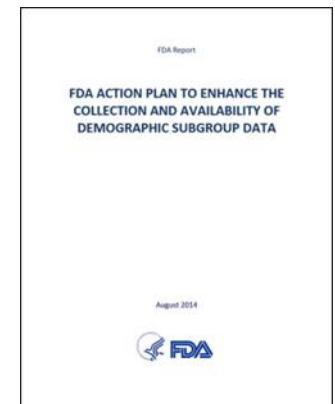
## **Priority Two: Identify barriers to subgroup enrollment in clinical trials and employ strategies to encourage greater participation (Participation)**

2.1 Seek further clarity regarding barriers to subgroup participation rates

2.2 Implement efforts to enhance appropriate use of enrollment criteria in clinical trial protocols

2.3 Increase collaboration with NIH, industry and other interested stakeholders to broaden diverse participation in clinical research; and

2.4 Utilize FDA's communication channels to encourage clinical trial participation by demographic subgroups



## Priority Three: Making demographic subgroup data more available and transparent (Transparency)

3.1 Post demographic composition and analysis by subgroup in pivotal clinical studies for FDA-approved medical products

3.2 Identify potential methods to consistently communicate meaningful information on demographic subgroups in medical product labeling

3.3 Implement communication strategies that are sensitive to the needs of underrepresented subpopulations (focus on language access and health literacy)

3.4 Establish an internal FDA steering committee to oversee and track implementation of the action plan and serve as planning group for an FDA workshop on the action plan



## Section 907 Action Plan, In Closing

Advances in science are also playing an increasingly important role in deepening our understanding of how patients within various subgroups respond to medical products.

- For example, information from areas such as **pharmacogenomics** is now being incorporated into product development and regulatory review to further address subgroup characteristics and population needs, helping to overcome the challenges of the “one-size-fits all” model of patient treatment.
- Ultimately, this is steering us towards the goal of tailoring treatments to individuals or subgroups of patients through **personalized medicine—including patients in underserved and underrepresented populations.**”





## For Additional Information and to Comment on the Action Plan

FDASIA 907updates: <http://go.usa.gov/v8YP>

Comment on FDAISIA 907 Action Plan:  
<http://go.usa.gov/v8gF> - Docket Closing October 21<sup>st</sup>

Via Email:

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# Thank You!

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