



Federal Inclusion Policy

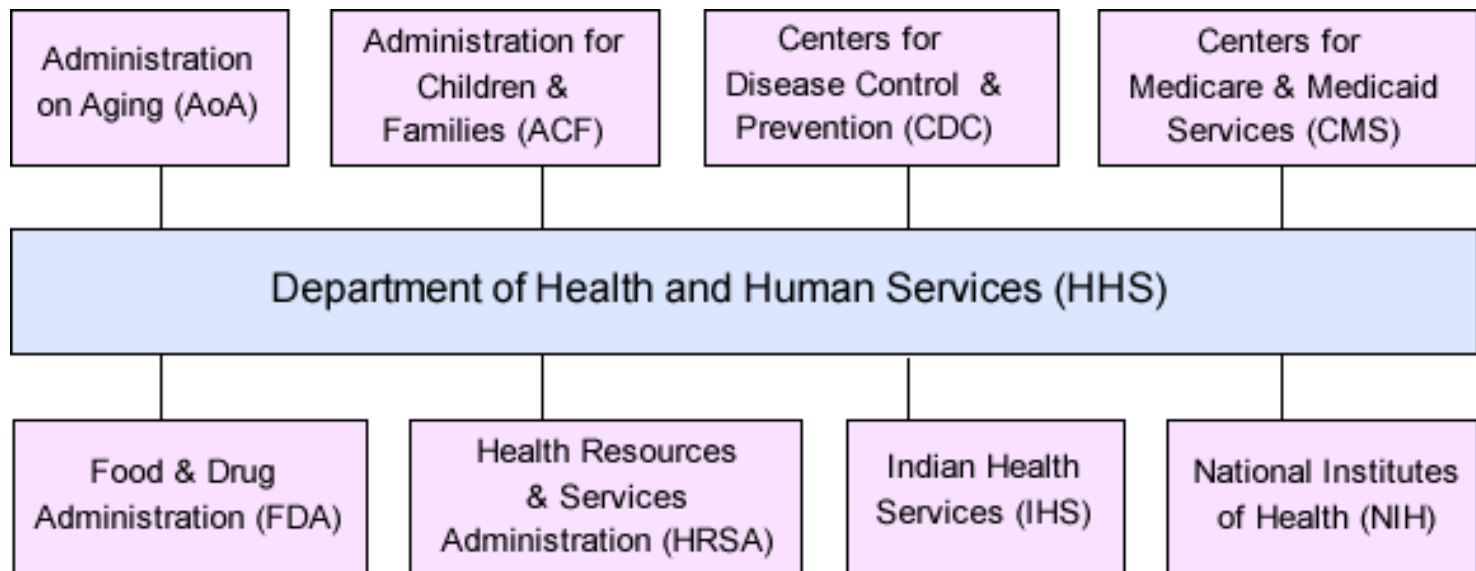
Holly Taylor, PhD, MPH

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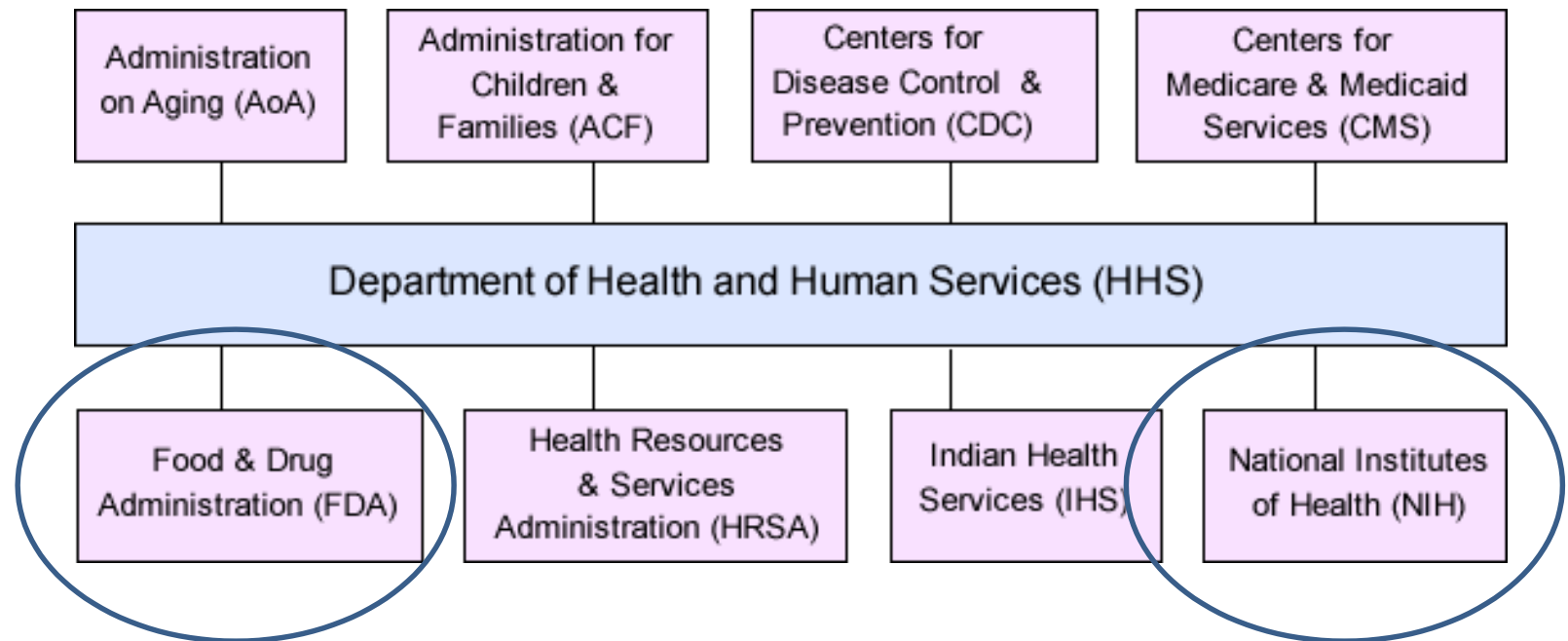
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**The views expressed in this talk are my own.
They do not represent the position or policy
of the NIH, DHHS, or US government**

US Department of Health and Human Services



US Department of Health and Human Services



National Institutes of Health

- NIH budget in FY 2022 was \$45 billion
 - 84% of NIH's funding is awarded for extramural research
 - 50,000 competitive grants to more than 300,000 researchers at more than 2,500 universities, medical schools, and other research institutions
 - 10% of NIH funding supports intramural research
 - 6,000 investigators, the majority in laboratories here in Bethesda

Source: NIH (2022)

National Institutes of Health

- **Inclusion of Women and Minorities in Clinical Research Policy (1986)**
- **NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research (1994, update 2001)**
- **NIH Policy and Guidelines on the Inclusion of Children as Subjects in Clinical Research (1998, update 2017)**
- **NIH Policy and Guidelines on the Inclusion of Individuals Across the Lifespan as Participants in Research Involving Human Subjects (2017)**

National Institutes of Health

- **Sex as a Biological Barrier (2016)**
 - Attention at earliest stages of development
- **No policy yet but recent attention to inclusion of:**
 - **Lesbian, Gay, Bisexual and Transgender People**
 - **People with disabilities**

Source: NIH (2022)

Food and Drug Administration

- Regulation of food, drugs, biologics, medical devices, electronic products that give off radiation, cosmetics and veterinary products.
 - Review the data submitted related to a drug or device and decide to approve or not

Food and Drug Administration

- **General Considerations for the Clinical Evaluation of Drugs (1977, withdrawn 1993)**
- **Guideline for the Format and Content of the Clinical and Statistical Sections of New Drug Applications (1988)**
- **Guideline for the Study of Drugs Likely to be Used in the Elderly (1989)**
- **Guideline for the Study and Evaluation of Gender Differences in the Clinical Evaluation of Drugs (1993)**

Source: NAS (2022)

Food and Drug Administration

- **Revision of New Drug Application, Demographic Rule (1998)**
- **Pregnant Women: Scientific and Ethical Considerations for Inclusion in Clinical Trials (2018)**
- **Action Plan to Enhance Collection and Availability of Demographic Subgroup Data (2014)**
- **Evaluation and Reporting of Age-, Race- and Ethnicity-Specific Data in Medical Device Studies (2017)**

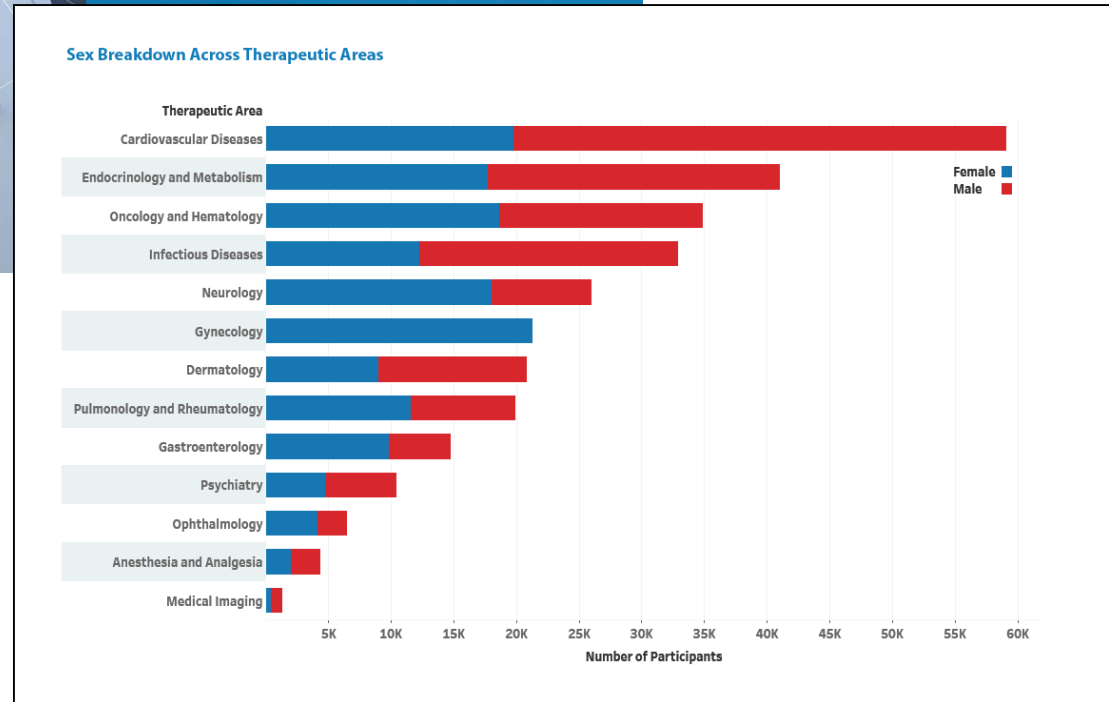
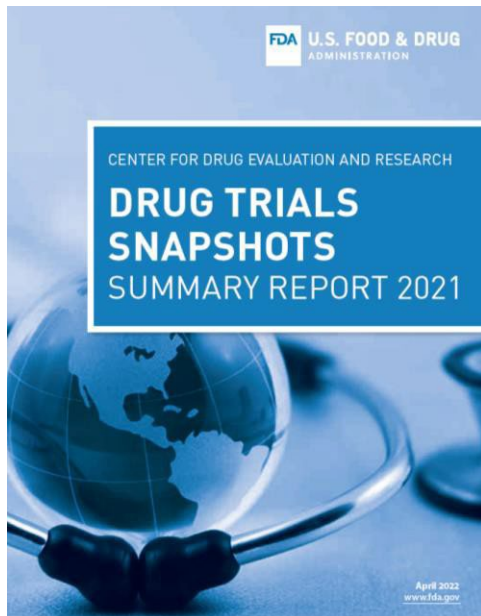
Source: NAS (2022)

Food and Drug Administration

- **Enhancing the Diversity of Clinical Trial Populations- Eligibility Criteria, Enrollment Practices and Trial Designs Guidance for Industry (2020)**
 - Some attention to inclusion of people with disabilities
 - Little attention to inclusion of sexual minorities

Source: NAS (2022)

Drug Trial Snapshots



Other Players

- **Government Accounting Office**
- **National Academy of Sciences**
 - **Improving Representation in Clinical Trials and Research: Building Research Equity for Women and Underrepresented Groups (2022)**