

# A Review of Expanded Access Programs

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Research

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# Expanded Access Program Survey

- Improve expanded access programs
  - Patients
  - Providers
  - Sponsors
- Questions
  - Who is/has benefited?
  - Is it reaching people most in need?

# Methodology

- **Search Terms:**
  - “Drug Name (Generic or Brand)” + Expanded Access Program
- **Electronic Databases**
  - PubMed, Medline, Scopus, Google Scholar
- **HIV/AIDS Service Organizations/Medical Information Websites**
  - Project Inform
  - The Body
  - AIDS Education Global Information System
  - National AIDS Treatment Advocacy Project
- **Pharmaceutical Company Websites**

# Confidential Information

- Darunavir
- TMC 125
- MK-0518 (raltegravir?)

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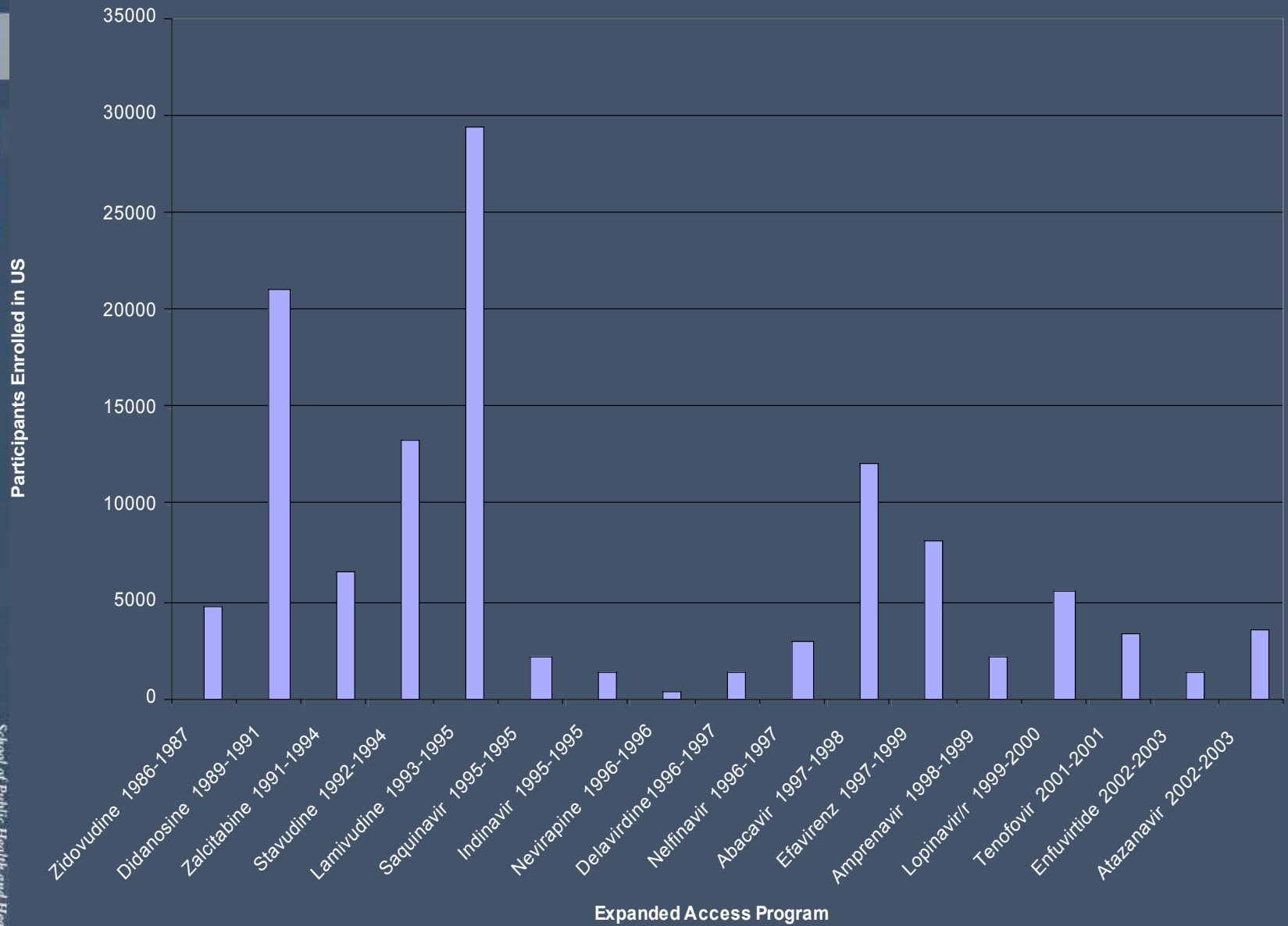
# Caveats to Findings

- Decentralized Information
  - Many sources have pieces of information
  - Pharmaceutical websites
    - Some have information about previous EAPs, others do not

# Caveats to Findings

- Limited Information
  - Some of the past EAPs results were not easily accessible
  - Inclusion/Exclusion Criteria
  - Demographics
    - Gender
    - Race/Ethnicity
  - Participation
    - Worldwide vs. United States
  - Sites
    - Location of site not usually provided

## Expanded Access Programs (1986-2006)



- MK-0518 – open EAP Program

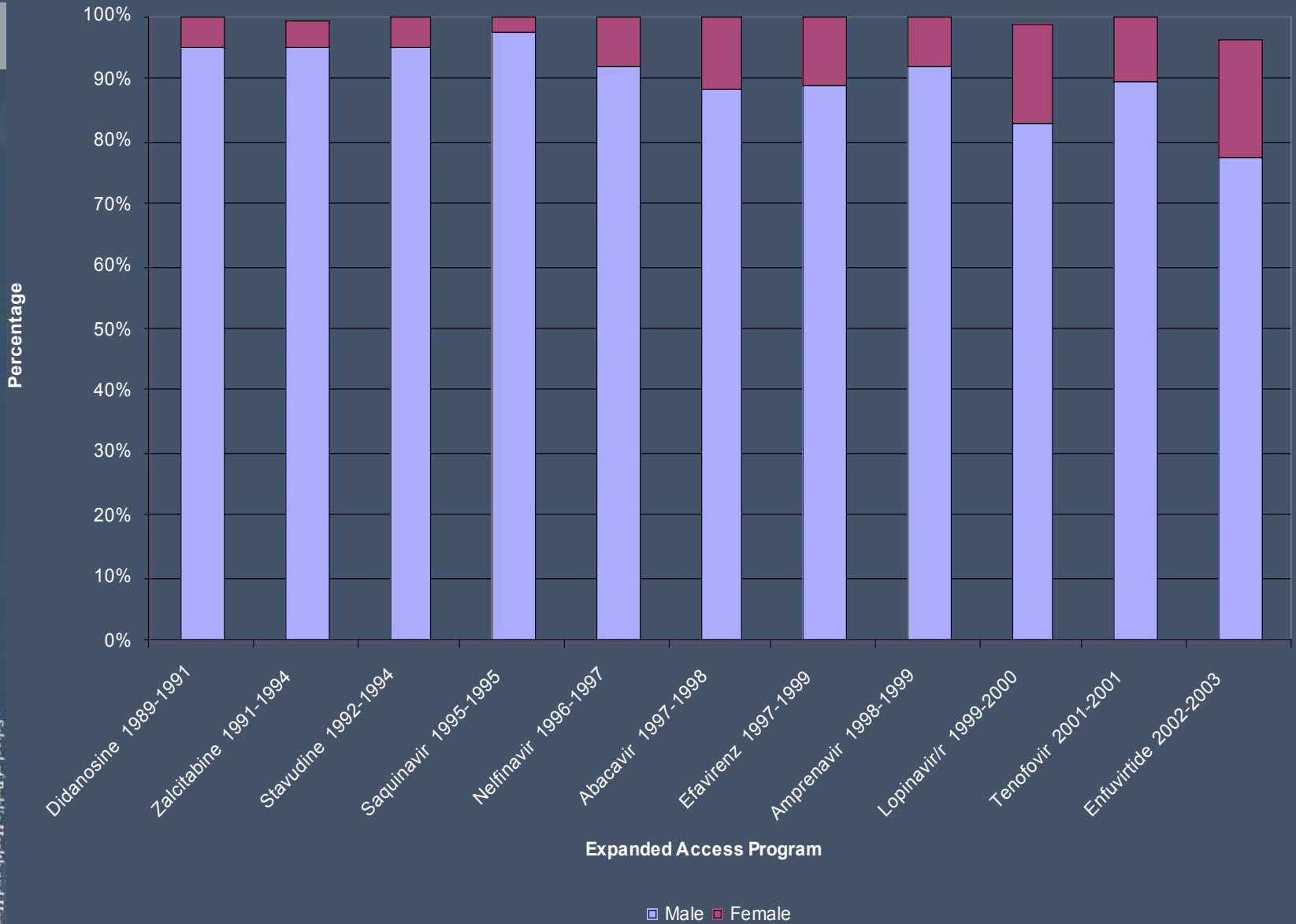
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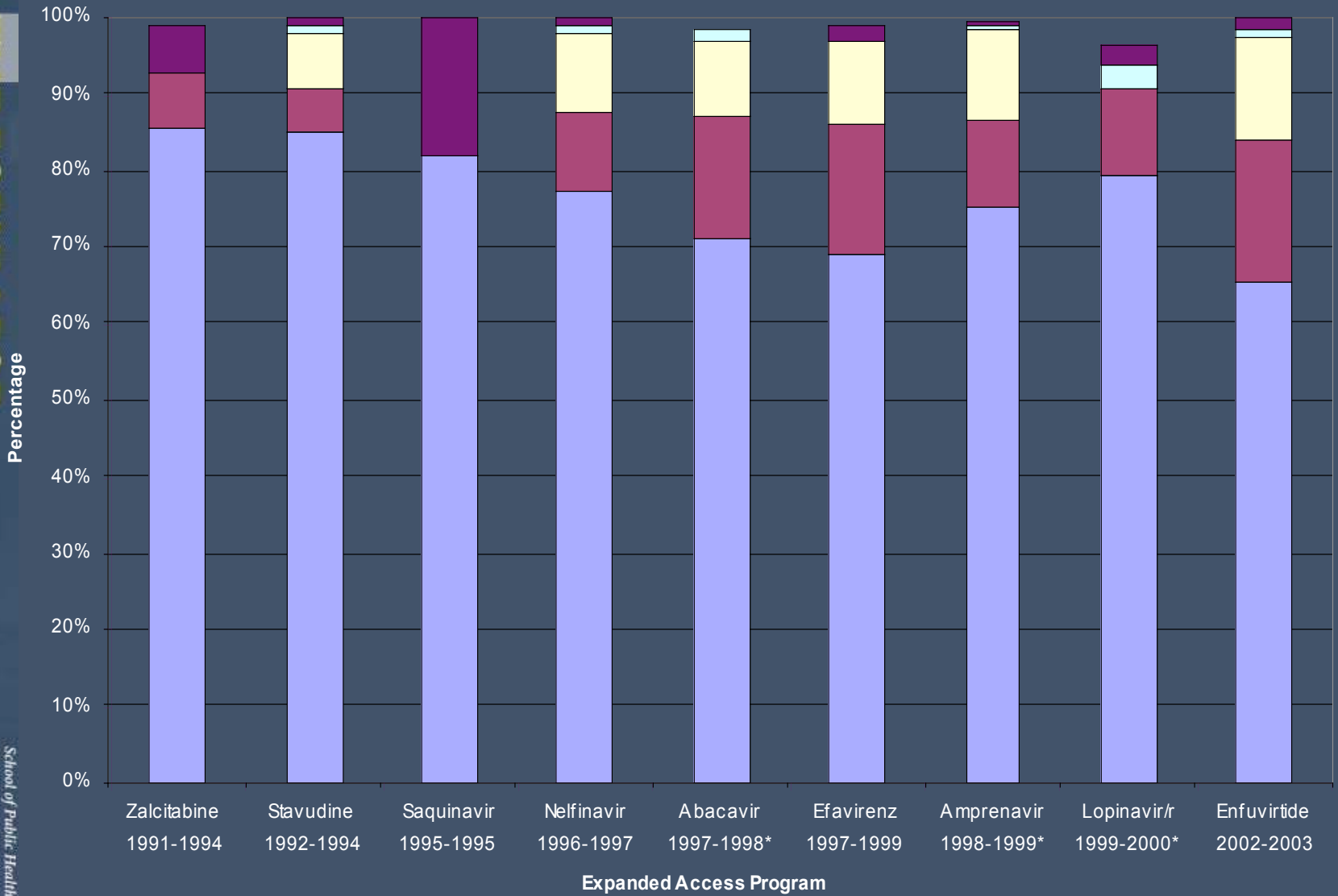
### Percentage of Males and Females in Expanded Access Programs



- Note: Missing Data for some of the expanded access programs



# US Expanded Access Programs By Race/Ethnicity



■ White 
 ■ Black 
 ■ Hispanic 
 ■ Asian 
 ■ Other

• \* Global Data

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# Findings

- Trends
  - Participation in EAPs since 1998 is decreasing
  - Disproportionate numbers of people of color and women participating in EAPs
  - Lack of accessible information for EAPs
  - Generally more recent EAPs have been shorter in duration (US only?)

# Acknowledgements

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