



NIAID: State of the Institute and Priorities in HIV/AIDS Research

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Director

**National Institute of Allergy and
Infectious Diseases**

National Institutes of Health

June 4, 2019



Legislative Update

116th Congress: House Leadership

- **Democrats win House majority**
 - **Speaker of the House: Rep. Nancy Pelosi (D-CA)**
 - **Minority Leader: Rep. Kevin McCarthy (R-CA)**



House Committee Leadership

■ House Appropriations Committee

- Chair: Rep. Nita Lowey (D-NY)
- Ranking Member: Rep. Kay Granger (R-TX)



■ Labor-HHS Subcommittee

- Chair: Rep. Rosa DeLauro (D-CT)
- Ranking Member: Rep. Tom Cole (R-OK)





Rep. Rosa DeLauro (D-CT)

**Chairwoman of the House Health and Human
Services Appropriations Subcommittee**

Senate Committee Leadership

■ Senate Appropriations Committee

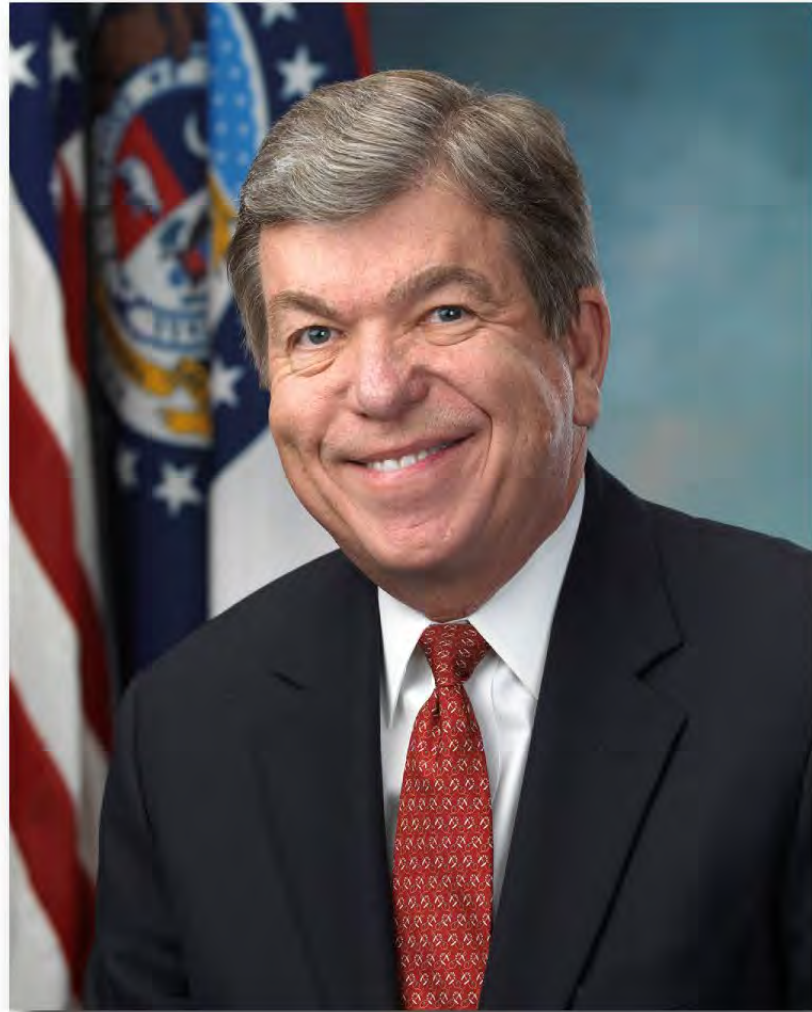
- Chair: Sen. Richard Shelby (R-AL)
- Ranking Member: Sen. Patrick Leahy (D-VT)



■ Labor-HHS Appropriations Subcommittee

- Chair: Sen. Roy Blunt (R-MO)
- Ranking Member: Sen. Patty Murray (D-WA)





Sen. Roy Blunt (R-MO)

**Chairman of the Senate Health and Human
Services Appropriations Subcommittee**

Budget Update

FY 2019 Budget for 8 Largest NIH Institutes

NCI	\$6.1B
NIAID	\$5.5B
NHLBI	\$3.5B
NIA	\$3.1B
NIGMS	\$2.9B
NINDS	\$2.3B
NIDDK	\$2.2B
NIMH	\$1.9B

Total NIH Budget (enacted): \$39.3B

FY 2020 President's Budget Request

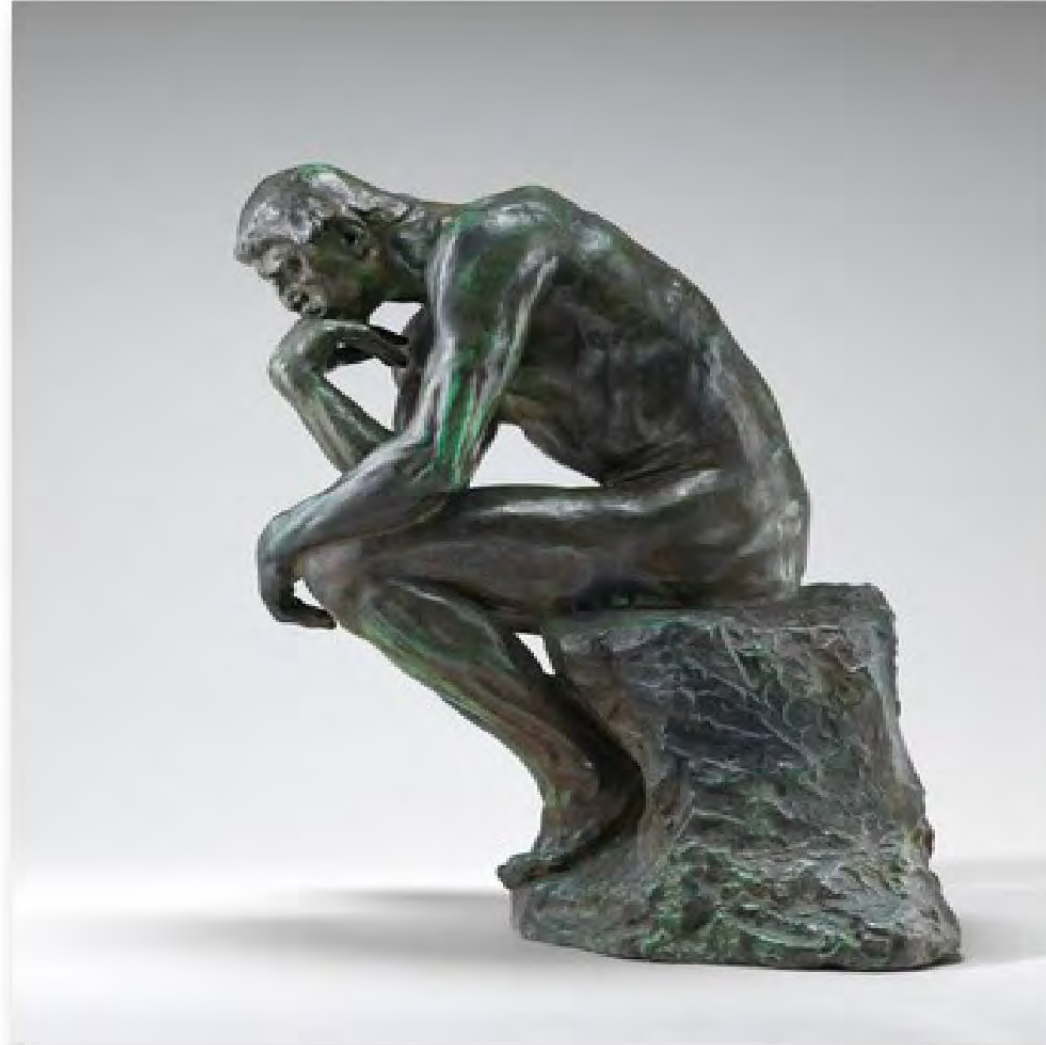


National Institutes of Health Budget Comparison by Institute/Center (Dollars in Thousands)

IC	FY 2019 Enacted	FY 2020 P.B.	Percent Change
NCI	\$ 6,143,892	\$ 5,246,737	-14.6%
NIAID*	5,567,230	4,792,182	-13.9%
NHLBI	3,488,335	3,002,696	-13.9%
NHGRI	575,579	495,448	-13.9%
NCATS	806,373	694,112	-13.9%
NIGMS*	2,828,874	2,435,035	-13.9%
NIA	3,083,410	2,654,144	-13.9%
NIDA	1,419,844	1,296,379	-8.7%
NIRSQ New in FY 2020	-	255,960	-
Other ICs	13,081,788	11,368,792	-13.1%
Subtotal	\$ 36,995,325	\$ 32,241,485	-12.8%
OD	2,117,675	1,926,144	-9.0%
B&F	200,000	200,000	0.0%
Total NIH Program Level	\$ 39,313,000	\$ 34,367,629	-12.6%

*Figures include AIDS portfolio transfers from NIGMS to NIAID: \$44M in FY 2019 and an estimated \$38M in FY 2020

How to Absorb a 13 Percent Cut in the NIH Base Budget?



**The President Proposes
a Budget**



**The Congress Determines
the Budget**

Science

House Panel Proposes \$2 Billion Increase for NIH

Jocelyn Kaiser

- **Draft bill by the House Appropriations Committee provides a total of \$41.1 billion for NIH for fiscal year 2020, an increase of \$2 billion above the 2019 enacted level and \$6.9 billion above the President's budget request.**



FY 2020 House Labor-HHS Appropriations Bill Report

“.... Furthermore, the Committee rejects the Administration’s proposal to cut NIH’s HIV research budget by more than \$400,000,000. Instead the Committee continues to invest in research that led to breakthroughs in current treatments such as PrEP and ART. The bill includes an increase of \$149,000,000 for NIH to continue funding research that could lead to an HIV vaccine or a cure.”

National Institutes of Health

Budget Comparison by Institute/Center

(Dollars in Thousands)

IC	FY 2019 Enacted	FY 2020 House Mark	Percent Change
NCI	\$ 6,143,892	\$ 6,444,165	4.9%
NIAID	5,523,324	5,808,268	5.2%
NHLBI	3,488,335	3,658,822	4.9%
NHGRI	575,579	603,710	4.9%
NCATS	806,373	845,783	4.9%
NIGMS	2,872,780	3,033,183	5.6%
NIA	3,083,410	3,286,107	6.6%
NIDA	1,419,844	1,489,237	4.9%
Other ICs	13,081,788	13,724,133	4.9%
Subtotal	\$ 36,995,325	\$ 38,893,408	5.1%
OD	2,117,675	2,219,592	4.8%
B&F	200,000	200,000	0.0%
Total NIH Program Level	\$ 39,313,000	\$ 41,313,000	5.1%

*Estimates made for Type I Diabetes (mandatory) and Superfund (non-HHS/Labor Appropriations) funding

HIV/AIDS Update

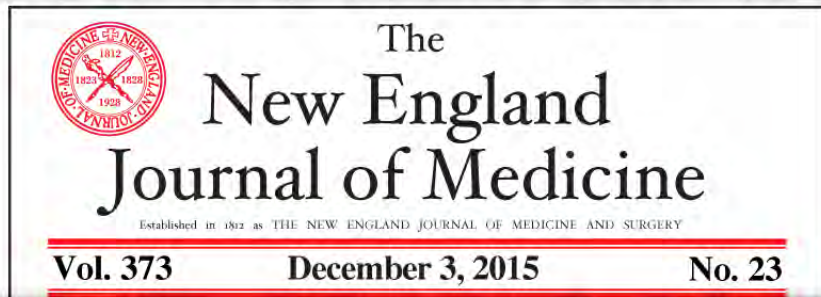
Ending the HIV Epidemic



Controlling and Ultimately Ending the HIV/AIDS Pandemic
GK Folkers and AS Fauci



Ending the HIV/AIDS Pandemic
RW Eisinger and AS Fauci



Ending the HIV-AIDS Pandemic – Follow the Science
AS Fauci and HD Marston



Ending the HIV Epidemic in the United States: Closing the Implementation Gaps
HD Marston, CW Dieffenbach and AS Fauci

Ending the HIV Epidemic



The Beginning of the End of AIDS?

D Havlir and C Beyrer



Goal of Ending AIDS Gains Traction

J Cohen



UNAIDS Board Calls for Ending the AIDS Epidemic as a Public Health Threat by 2030



A Prescription for Ending the HIV Epidemic

J Mermin and A Laxton

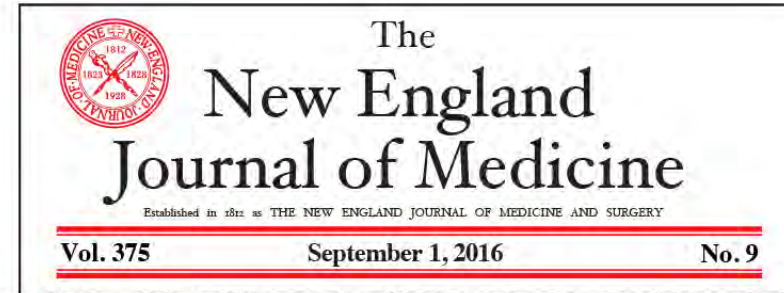
**Scientific Basis
for the Plan:
We have the Tools**

The Pivotal HPTN 052 Study



Prevention of HIV-1 Infection with Early Antiretroviral Therapy

HPTN 052 Study Team



Antiretroviral Therapy for the Prevention of HIV-1 Transmission

HPTN 052 Study Team

- 1,763 HIV-serodiscordant couples in 9 countries
- 96% reduction in HIV transmission when ART started in HIV-infected partner at CD4 count of 350-550 compared to <250

- After 5+ years of follow-up, protective effect of early ART was sustained (93% lower risk)

- No linked infections when HIV was stably suppressed by ART (i.e. undetectable viral load) in HIV⁺ partner

Major Studies Demonstrating Treatment as Prevention

- PARTNER Study (2016); 58,000 acts of condomless sex
- Opposites Attract (2018); 16,800 acts of condomless sex
- PARTNER 2 Study (2019); 76,088 acts of condomless sex

These studies showed no linked HIV transmissions involving a total of 150,888 acts of condomless sex when the partner with HIV was stably suppressed by ART

JAMA

THE JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION

February 5, 2019

Volume 321
Number 5

Viewpoint

HIV Viral Load and Transmissibility of HIV Infection

Undetectable Equals Untransmittable

RW Eisinger, CW Dieffenbach, and AS Fauci

HIV Pre-Exposure Prophylaxis (PrEP)



One pill per day



**>95% effective in
preventing HIV
acquisition**

The Fundamental Scientific and Clinical Basis for the Plan to End the HIV Epidemic in the United States

**Treatment
as Prevention
(TasP)**



**Pre-Exposure
Prophylaxis
(PrEP)**

Evolving Concept in Addressing HIV

**Saving lives,
alleviating
suffering,
preventing new
infections**



**Saving lives,
alleviating
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infections**



**Ending the
epidemic**

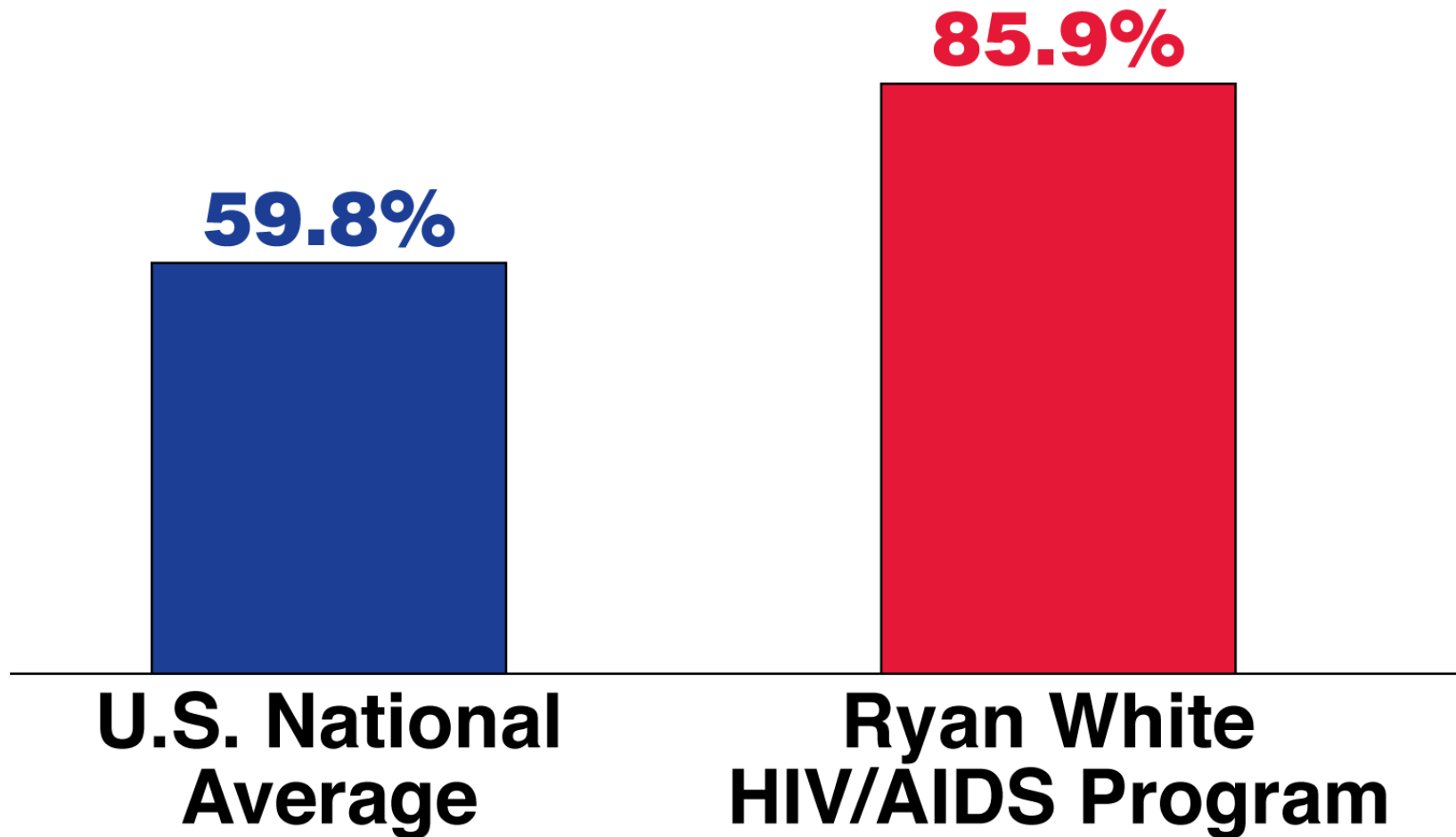
Theoretically, if we accessed and put on antiretroviral therapy everyone who has HIV and provide PrEP for all at high risk of HIV, we could rapidly end the epidemic.

Ending the HIV Epidemic in the United States



**The Implementation
Gap in Addressing the
HIV Epidemic in the
United States**

Rates of Viral Suppression in People Diagnosed with HIV Infection, United States



HIV Pre-Exposure Prophylaxis (PrEP) is Underutilized

- 1.1 million individuals in United States are at substantial risk for HIV and should be offered PrEP (CDC)
- Estimated number of U.S. PrEP users, end-2018: 269,000 (AVAC PrEPWatch, 2/2019)

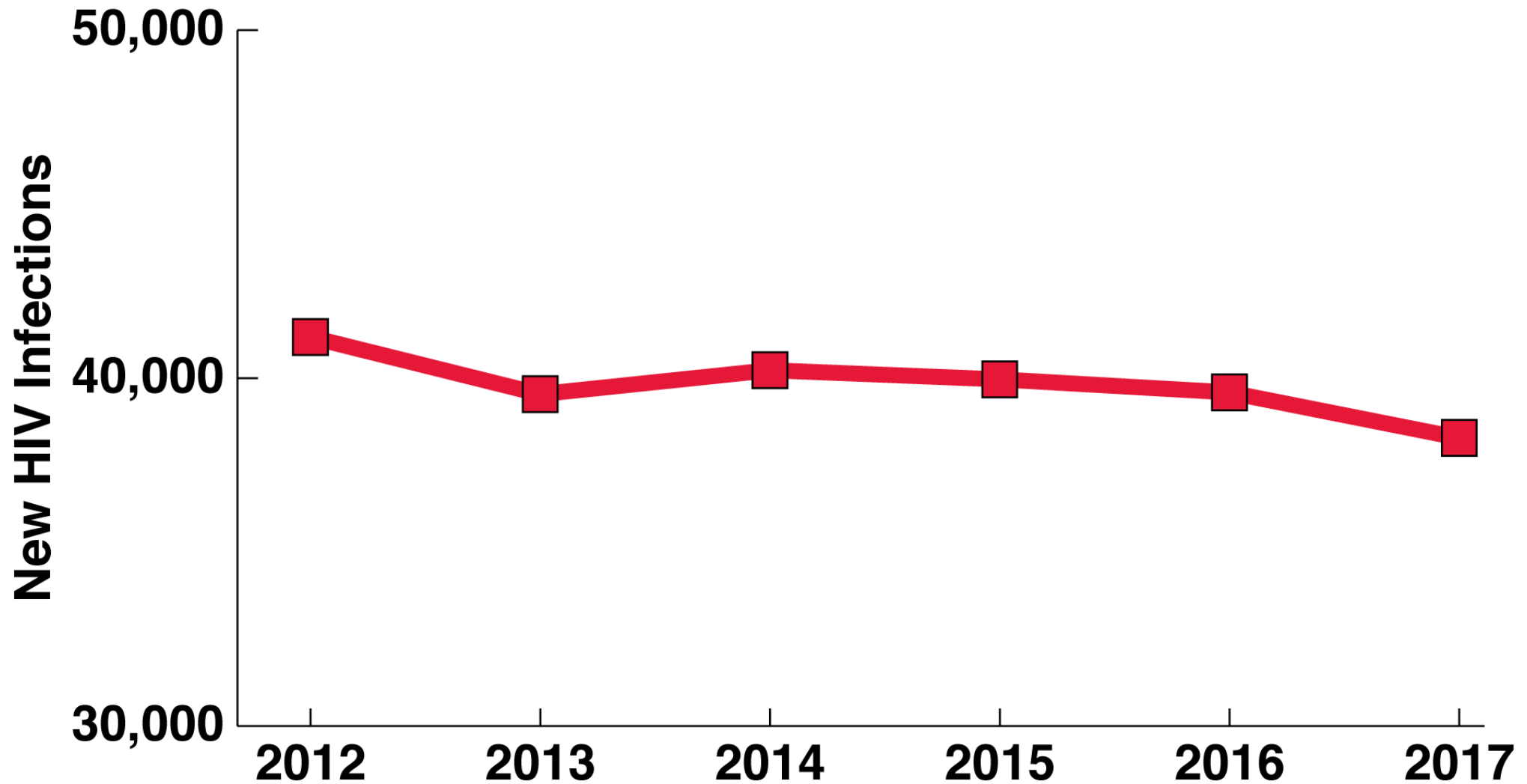


Being PrEPared – Preexposure Prophylaxis and HIV Disparities

RH Goldstein, CG Streed, SR Cahill

Beyond the cost of the medication, stigma and distrust of the medical system prevent at-risk people of color from obtaining and benefiting from PrEP.

Diagnoses of HIV Infection, United States, 2012-2017



Source: CDC HIV Surveillance Report, 2017; vol. 29, 11/2018.

October 29, 2012

NEJM

Journal Watch

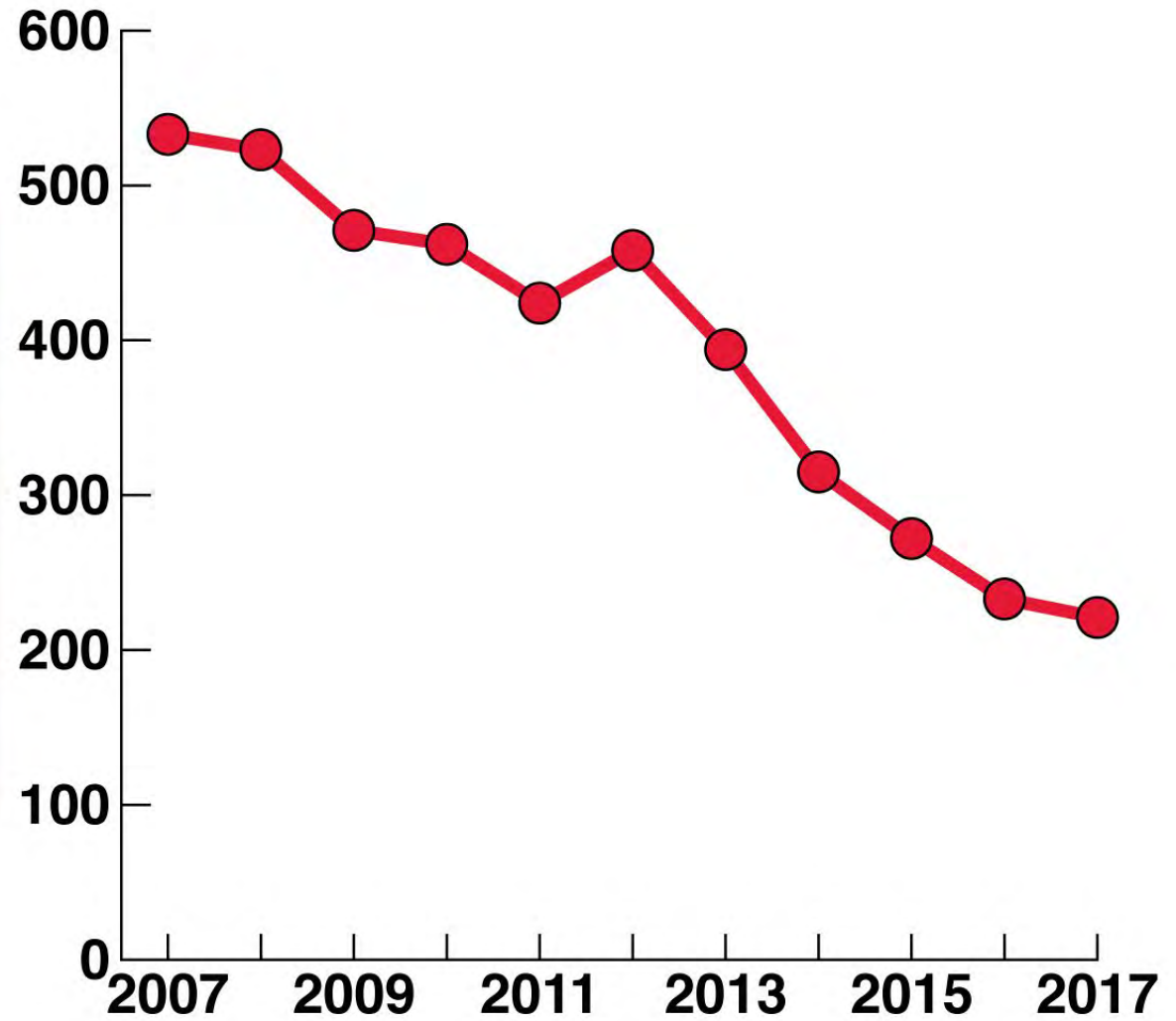
**"Treat All" Policy Proves
Effective in San Francisco**

January 7, 2019

Avert >

**'RAPID' HIV Treatment Initiation
a Success in San Francisco**

New HIV Diagnoses in San Francisco, 2007-2017



Source: SF Dept. of Public Health

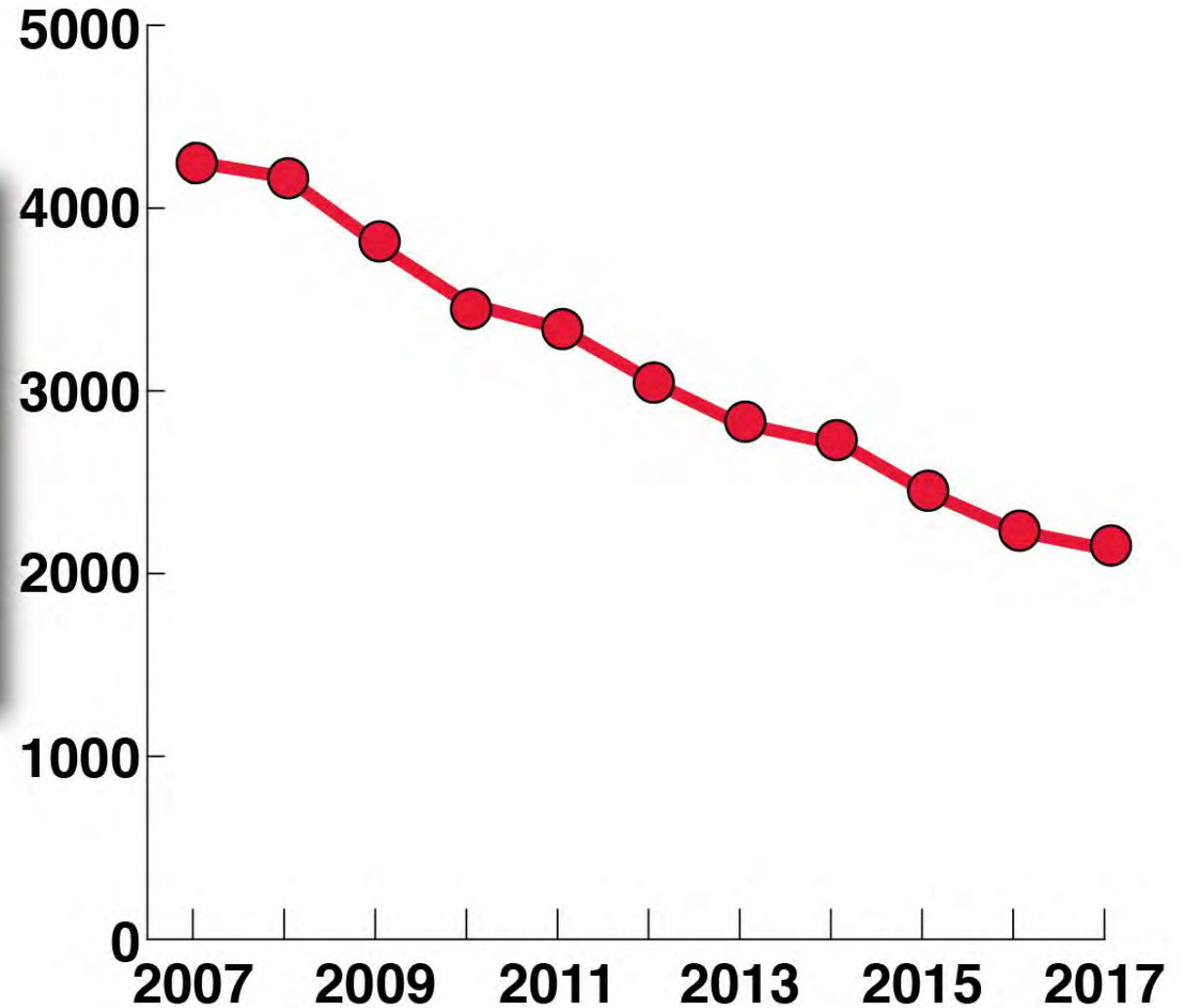
The New York Times

April 30, 2015

Cuomo Announces Plan to Cut New AIDS Cases in New York



New HIV Diagnoses in New York City, 2007-2017



Source: NYC DoH



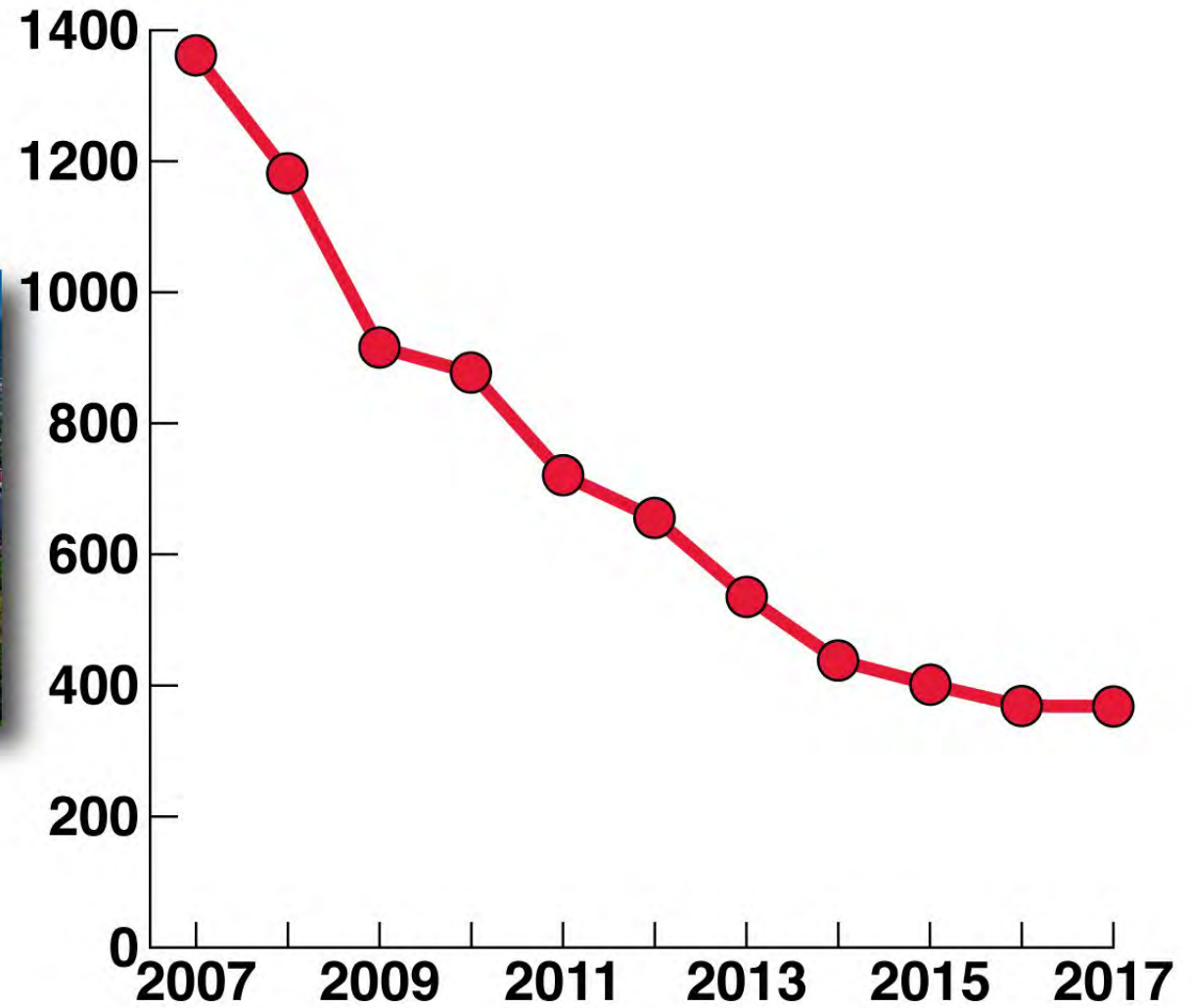
December 1, 2016

**Mayor Bowser
Announces
90/90/90/50 Plan to
End the District's HIV
Epidemic**



Mayor Muriel Bowser

New HIV Diagnoses in Washington, DC, 2007-2017



Source: DC Dept. of Health

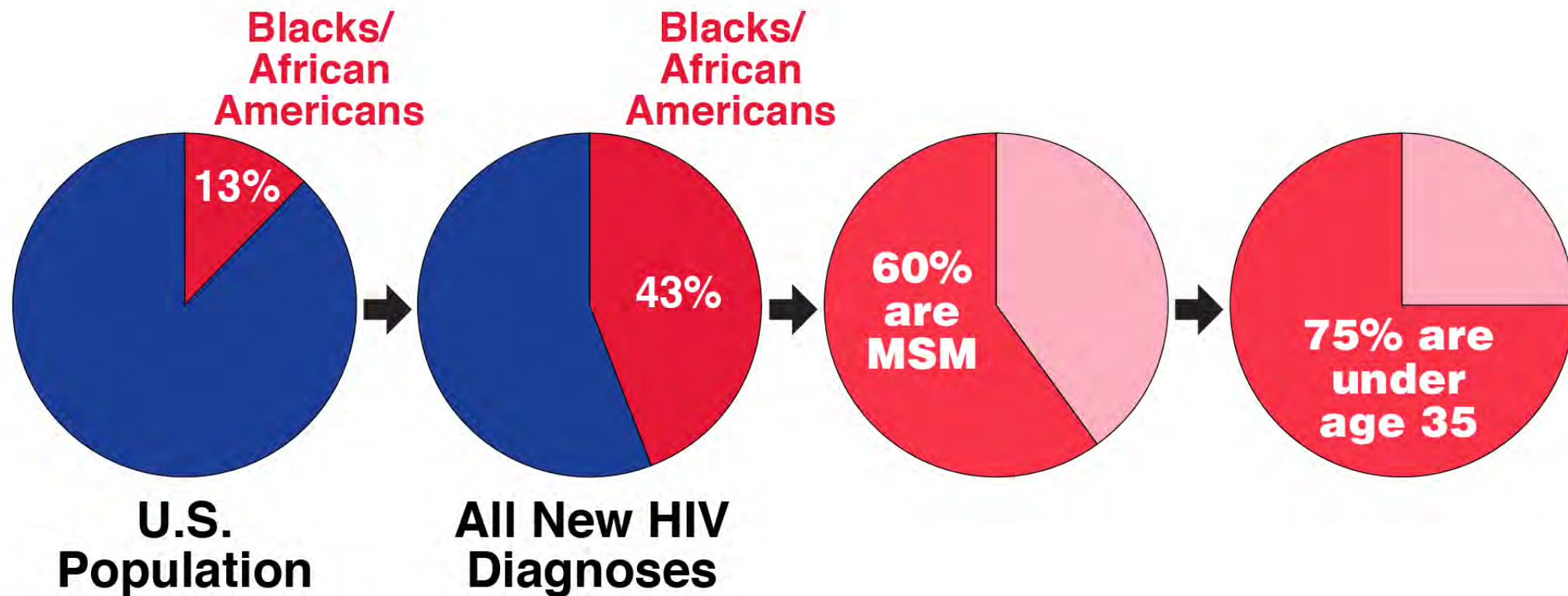
Ending the HIV Epidemic: A Plan for the United States



Incidence “Hot Spots”

Demographic Hot Spots

Demographic Hot Spots of HIV Infection: United States

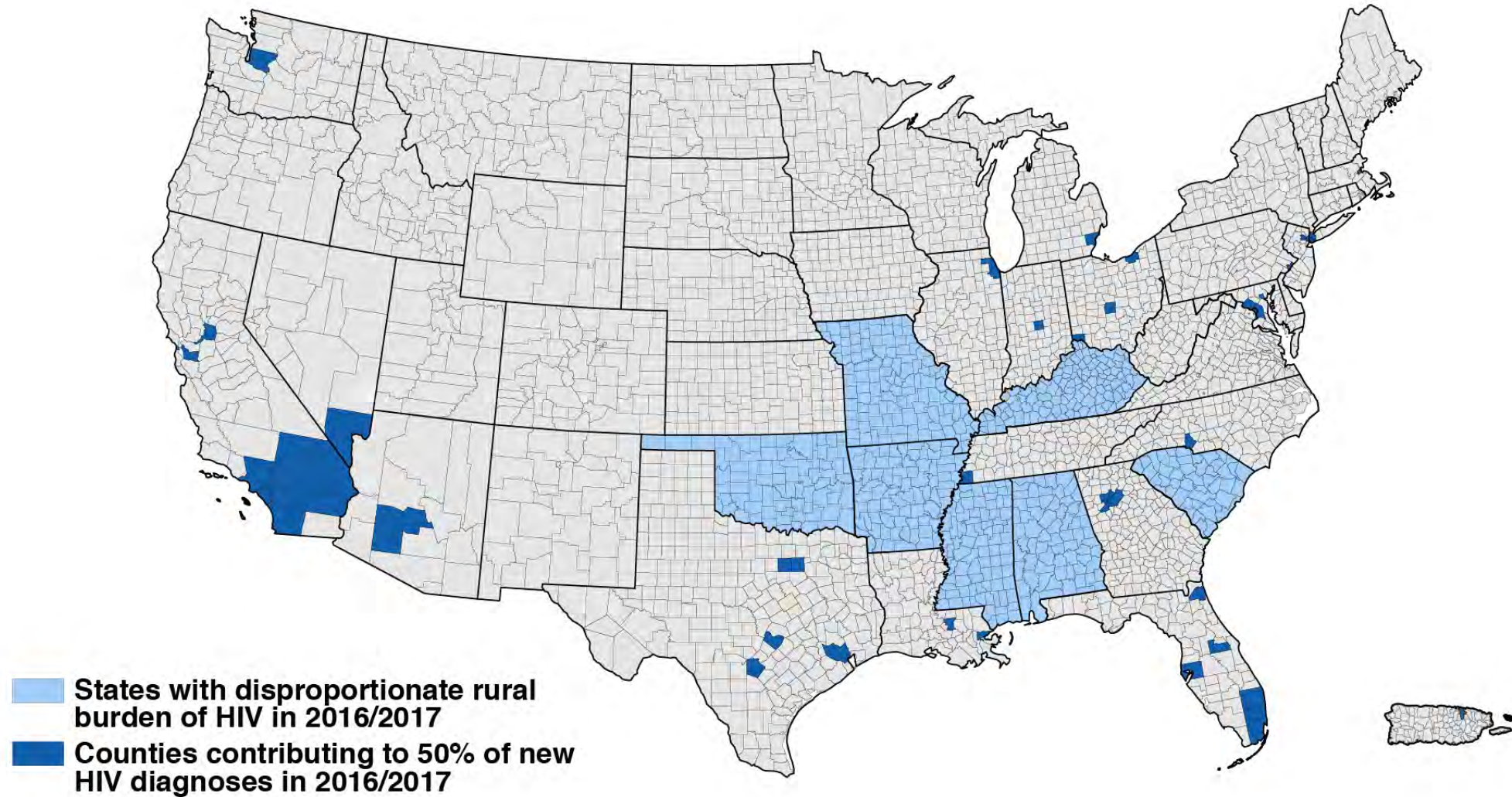


Geographic Hot Spots

Major Geographic and Demographic Disparities for HIV Incidence in the U.S.

- **3007 counties in the United States**
- **During 2016-2017, > 50% of new HIV infections occurred in 48 counties, Washington, DC and Puerto Rico**
- **Majority of new HIV infections among Black/African American and Hispanic/Latino MSM; high incidence among transgender individuals and IDUs**
- **7 mostly southern states have a disproportionate occurrence of HIV in rural areas**

U.S. Areas with the Highest Burden of HIV Diagnosis



The Washington Post

March 21, 2018

Longtime AIDS Researcher Robert Redfield Picked to Lead CDC





Alex M. Azar II
Secretary HHS



Robert R.
Redfield



Anthony S.
Fauci



Brett P. Giroir
**Assistant
Secretary
for Health**



George
Sigounas



Michael D.
Weahkee



Elinore F.
McCance-Katz

The Washington Post

February 5, 2019

**Trump Announces Goal of Ending
HIV/AIDS Epidemic by End of
Next Decade**

JAMA
THE JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION

March 5, 2019

Volume 321
Number 9

Editorial

Ending the HIV Epidemic A Plan for the United States

**AS Fauci, RR Redfield, G Sigounas, MD Weahkee,
and BP Giroir**

Ending the HIV Epidemic: A Plan for America

Goal:

75%
reduction
in new HIV
infections
in 5 years
and at least

90%
reduction
in 10 years.



Diagnose all people with HIV as early as possible after infection.

Treat the infection rapidly and effectively to achieve sustained viral suppression.



Protect people at risk for HIV using potent and proven prevention interventions, including PrEP, a medication that can prevent HIV infections.

Respond rapidly to detect and respond to growing HIV clusters and prevent new HIV infections.



Roles of the HHS Agencies in the Plan



Overall coordination of the plan



Intensification of existing programs with communities, state and local health authorities for HIV testing, diagnosis, epidemiologic investigation of clusters and rapid linkage to HRSA Ryan White HIV/AIDS Program (RWHAP)



Accelerate RWHAP treatment and care for those with HIV and provide PrEP for those at risk through the HRSA Health Centers Program



Focus on urban and rural tribal communities to expand access to diagnosis, prevention and treatment of HIV



Focus on Minority AIDS Program and Substance Abuse Prevention and Treatment Block grants for HIV/AIDS prevention for those with substance abuse or mental illness



Implementation science: collect and disseminate data on the effectiveness of approaches used in the initiative and inform HHS partners on best practices

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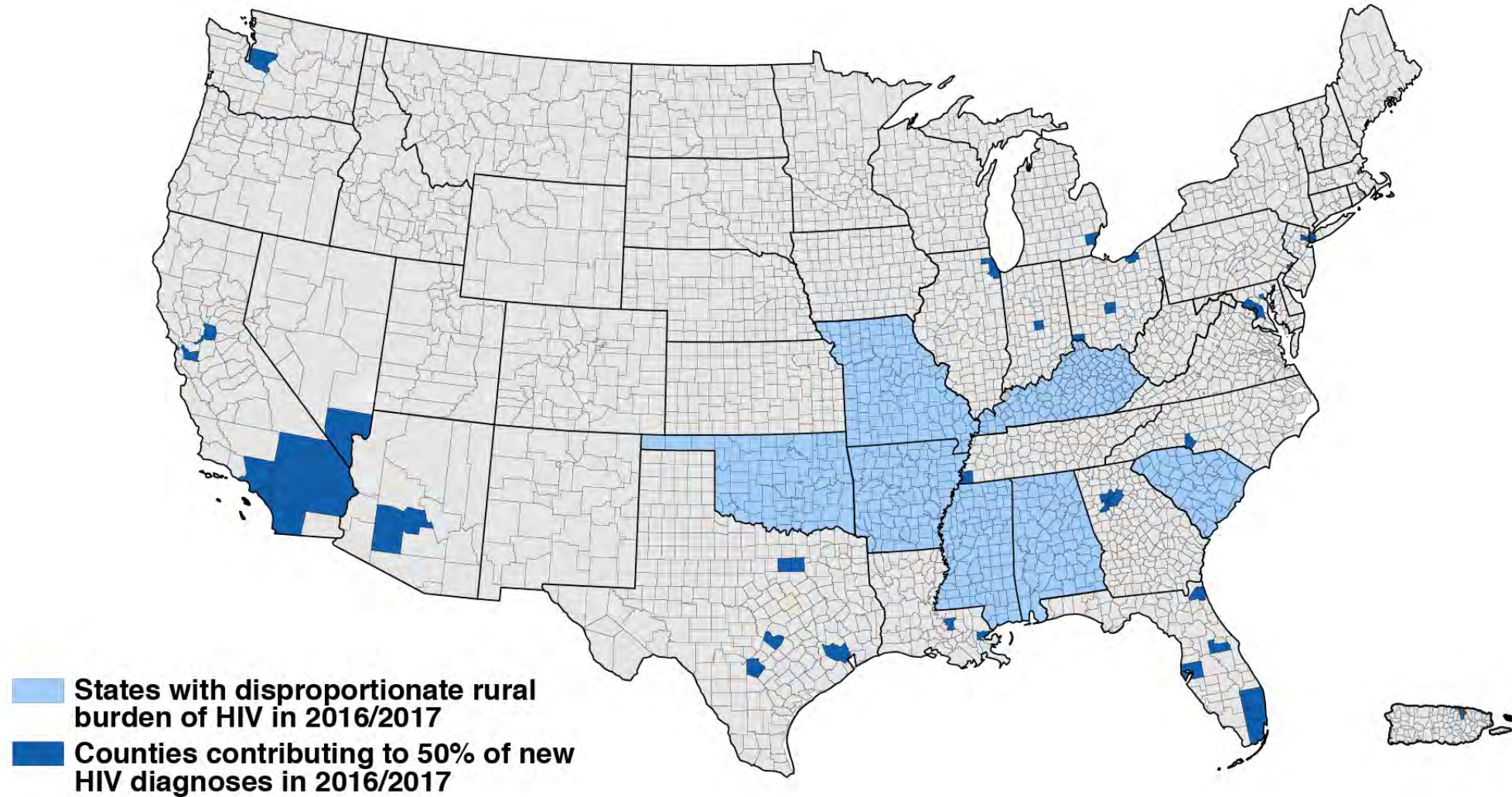


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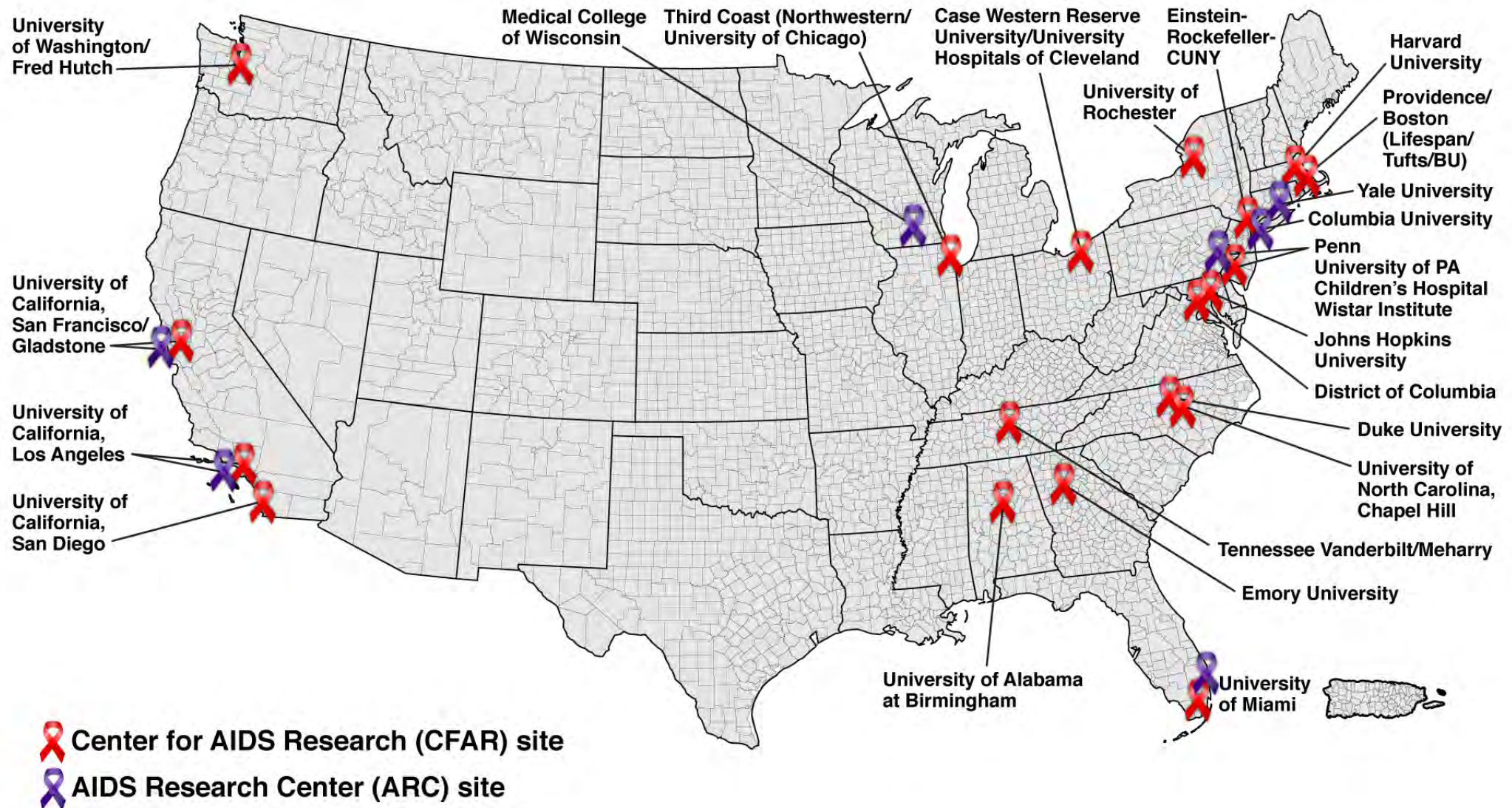


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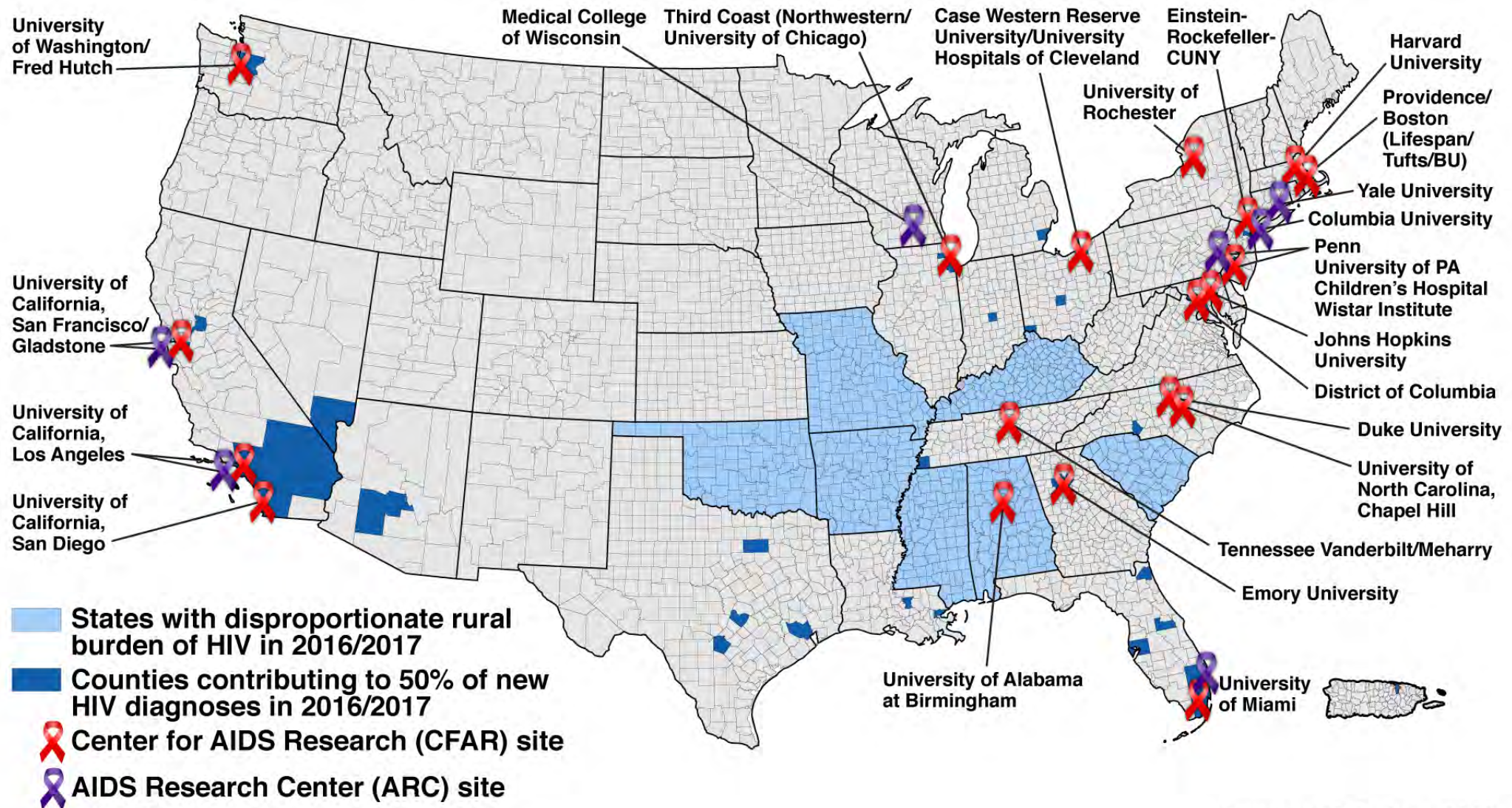
U.S. Areas with the Highest Burden of HIV Diagnosis



NIH-sponsored Centers for AIDS Research (CFAR) and AIDS Research Centers (ARC)



CFAR and ARC Sites and HIV Hotspots in the United States



What is new and different about this initiative and why are we optimistic that it will succeed?



It is the first time that an accelerated effort to implement HIV treatment and prevention in the U.S. has been simultaneously undertaken by multiple HHS agencies focused on highly specific and concentrated target populations

The Washington Post

January 10, 2016

OPINIONS

No More Excuses. We Have the Tools to End the HIV/AIDS Pandemic.

Anthony S. Fauci