



**NORTH
DALLAS**
CHAMBER OF
COMMERCE

ANNUAL
**HEALTH CARE
CONFERENCE**



The Future of America's Health: *And the Impact of Innovation*

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THE STATE OF AMERICA'S HEALTH

▶ U.S. Healthcare Spending

- \$3.8 trillion in 2019 (17.7% of GDP) expected to reach \$6.2 trillion (19.7% of GDP) by 2028

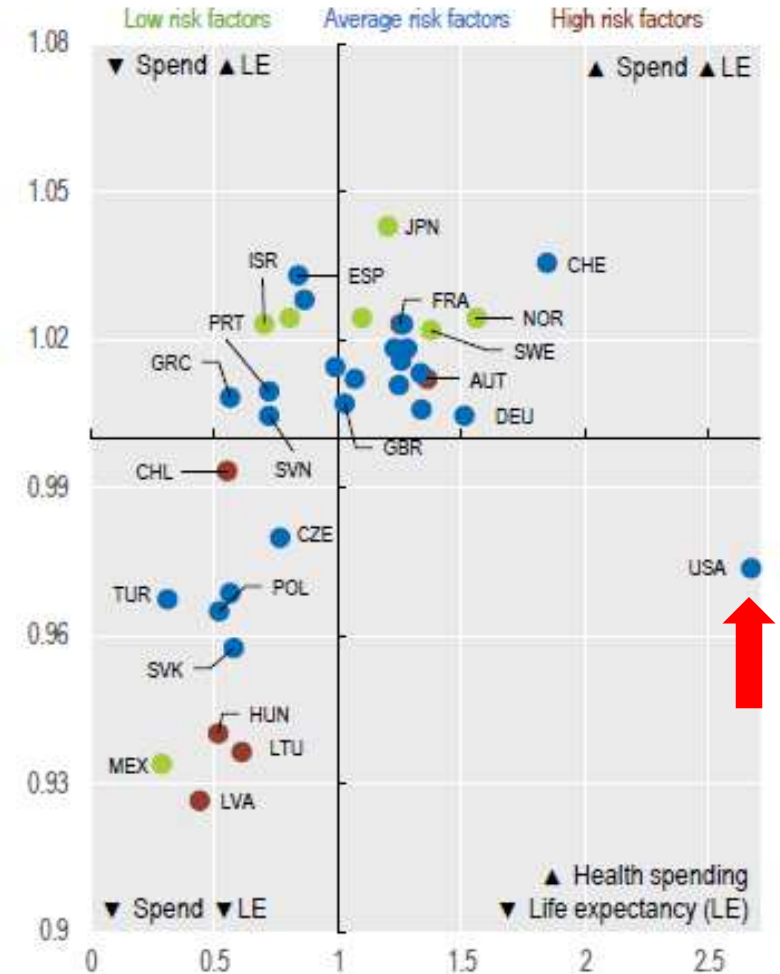
▶ Life Expectancy

- Among the 44 OECD nations, the U.S. ranks 28th in life expectancy; 34th in infant mortality; 33rd in suicide rate (2019); 32nd (of 38) in preventable mortality
- In 2015 and 2017 (and 2020), life expectancy **decreased** in the United States

▶ Chronic Health Conditions

- 90% of annual health expenditures are for people with chronic medical or mental conditions

Sources: CMS National Health Expenditure Projections 2019-2028
 OECD: Health at a Glance, 2021



Life Expectancy and Health Expenditure

U.S. HEALTH CHALLENGES IN THE 21ST CENTURY

WSJ

Recruits' Ineligibility Tests the Military

More Than Two-Thirds of American Youth Wouldn't Qualify for Service, Pentagon Says



“...the Defense Department estimates 71% of the roughly 34 million 17- to 24-year-olds in the U.S. would fail to qualify to enlist in the military if they tried....”

Physical Fitness, Drug Abuse, Education

STATUS OF THE PANDEMIC: US Daily Reported Cases



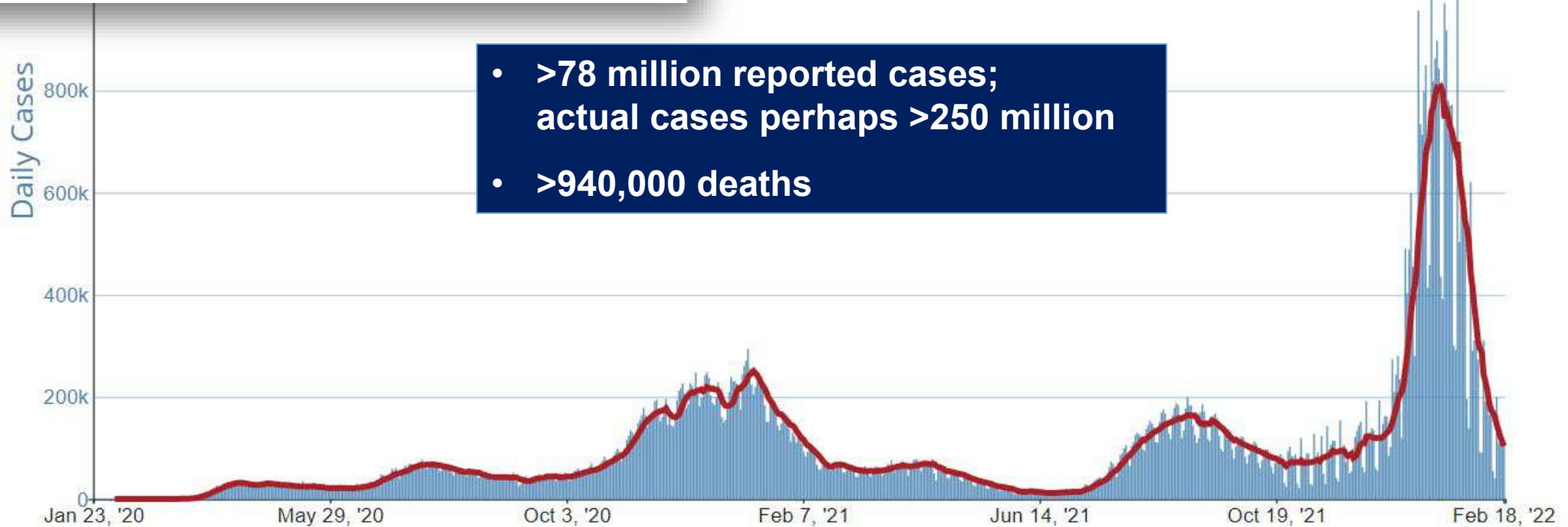
World Health Organization (WHO) @WHO · Jan 4, 2020

#China has reported to WHO a cluster of #pneumonia cases —with no deaths— in Wuhan, Hubei Province 🇨🇳. Investigations are underway to identify the cause of this illness.

87

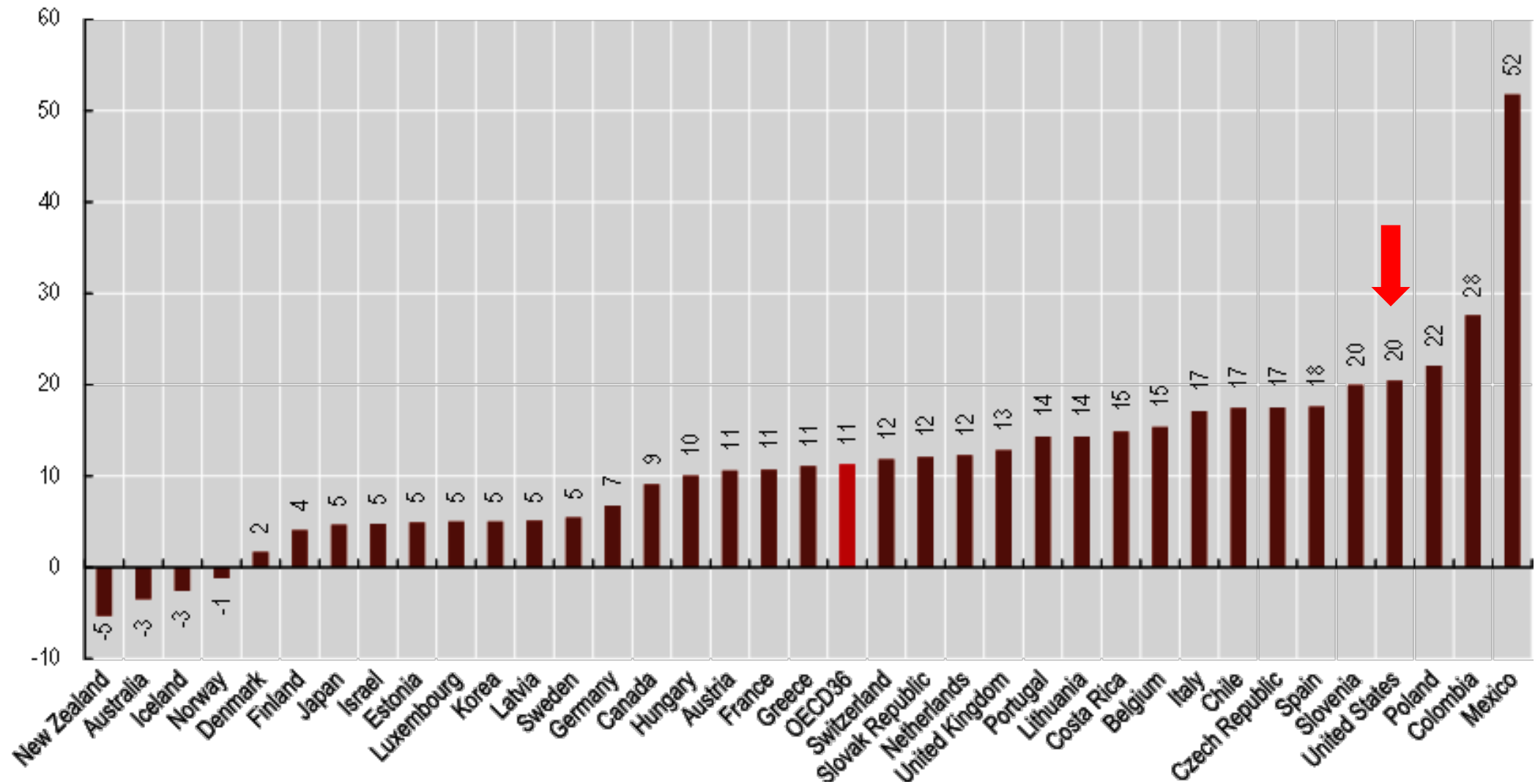
1K

777

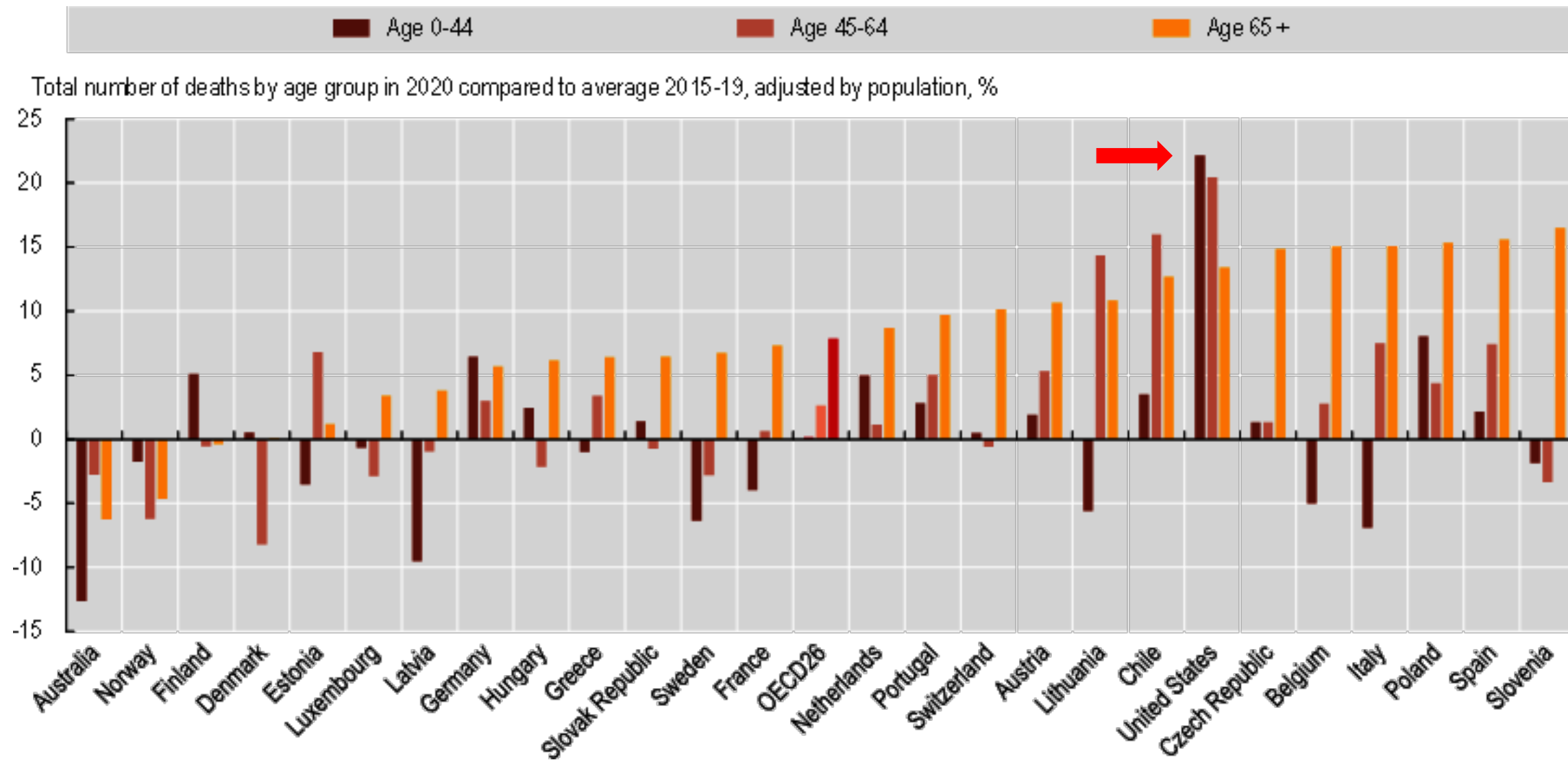


- Data from February 20, 2022
- CDC estimated 146 million COVID infections in US by September 2021

TOTAL EXCESS MORTALITY IN 2020 COMPARED TO 2015-2019



AGE DISTRIBUTION OF EXCESS MORTALITY



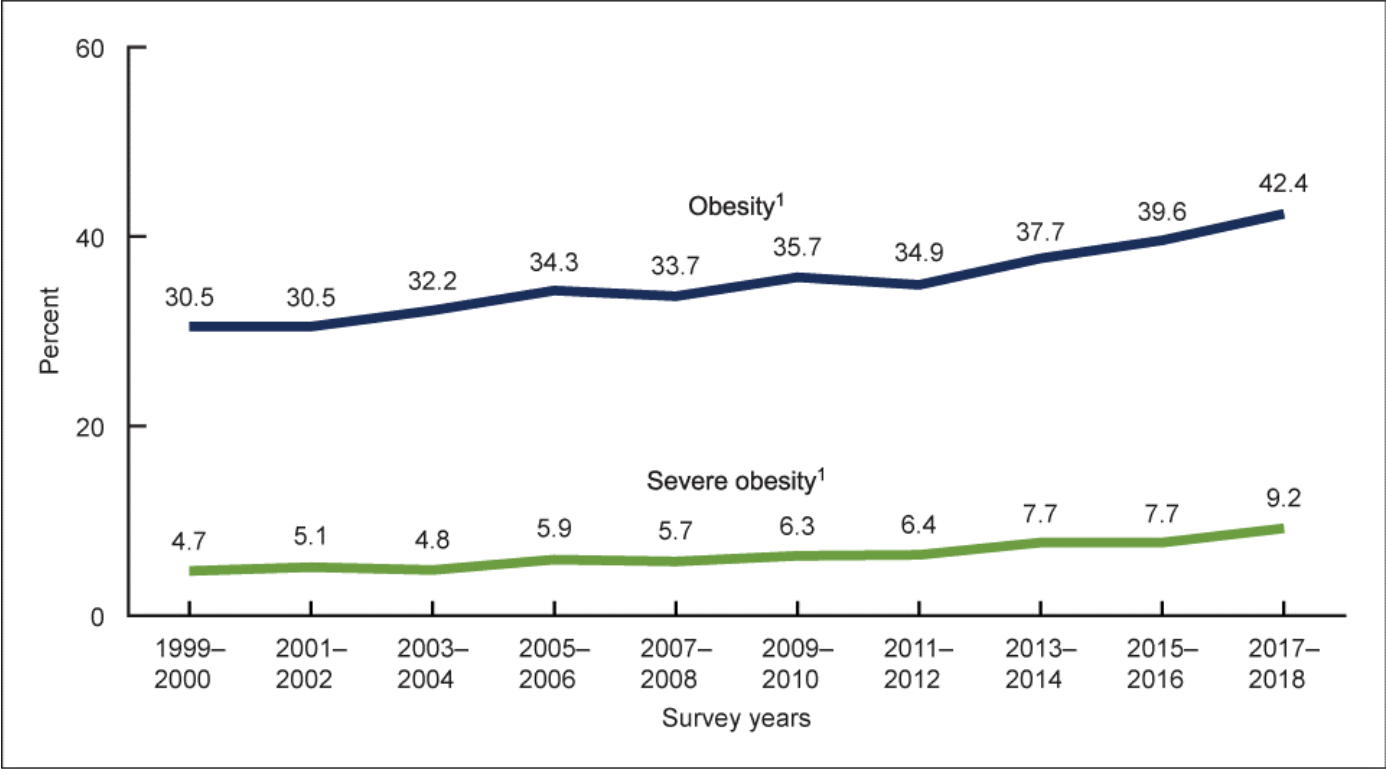
**THE COVID-19 PANDEMIC HAS
WORSENER AMERICA'S HEALTH STATUS
ACROSS NEARLY EVERY PARAMETER**

OBESITY IN THE UNITED STATES (2017-2018)

The age-adjusted prevalence of obesity in the United States among adults was 42.4% in 2017-2018

9.2% of US adults were severely obese

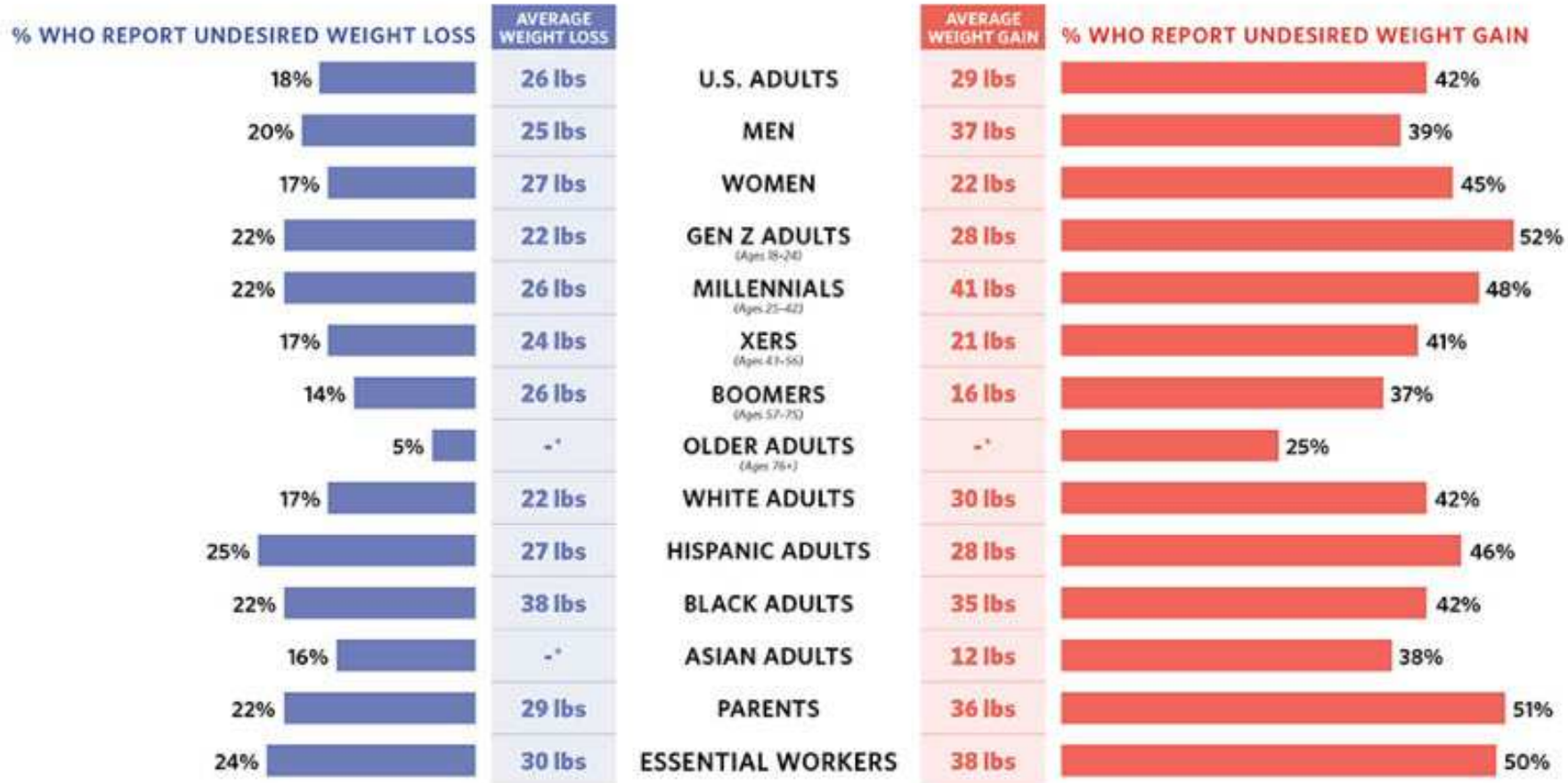
Trends in age-adjusted obesity and severe obesity prevalence among adults aged 20 and over: United States 1999-2000 through 2017-2018



¹Significant linear trend.
NOTES: Estimates were age adjusted by the direct method to the 2000 U.S. Census population using the age groups 20-39, 40-59, and 60 and over. Access data table for Figure 4 at: https://www.cdc.gov/nchs/data/databriefs/db360_tables-508.pdf#4.
SOURCE: NCHS, National Health and Nutrition Examination Survey, 1999-2018.

PANDEMIC SURVEY

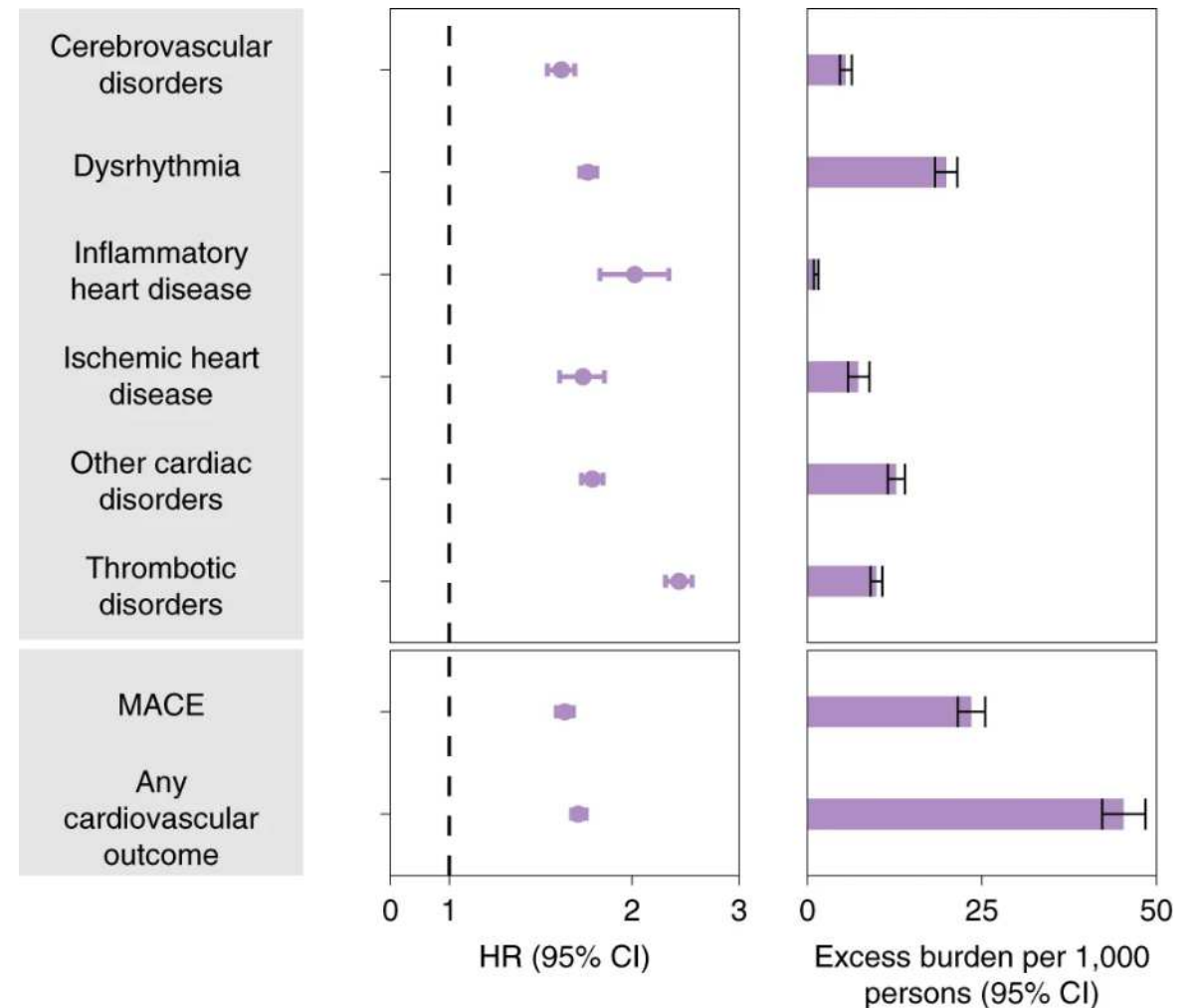
Slightly More Than 6 in 10 U.S. Adults (61%) Report Undesired Weight Change Since Start of Pandemic



Long-term cardiovascular outcomes of COVID-19

Yan Xie^{1,2,3}, Evan Xu^{1,4}, Benjamin Bowe^{1,2} and Ziyad Al-Aly^{1,2,5,6,7} ✉

- ...the risks and 12-month burdens of cardiovascular diseases reported here might translate into a large number of potentially affected people around the world.
- Governments and health systems around the world should be prepared to deal with the likely significant contribution of the COVID-19 pandemic to a rise in the burden of cardiovascular diseases.



A CRISIS OF UNDIAGNOSED CANCERS IS EMERGING IN THE PANDEMIC'S SECOND YEAR

ANALYSIS | BY [PROPUBLICA](#) | MAY 04, 2021

Englum et al; Cancer, December 2021

National Multicenter Study from VA Health System. Compared to 2018 and 2019, in 2020:

- Colonoscopies ↓ by 45%
- Prostate biopsies ↓ by 29%
- Cystoscopies ↓ by 21%.

New cancer diagnoses decreased by 13% to 23%.

Yabroff et al., J National Cancer Institute, June 2021

In 2020, cancer pathology reports declined for:

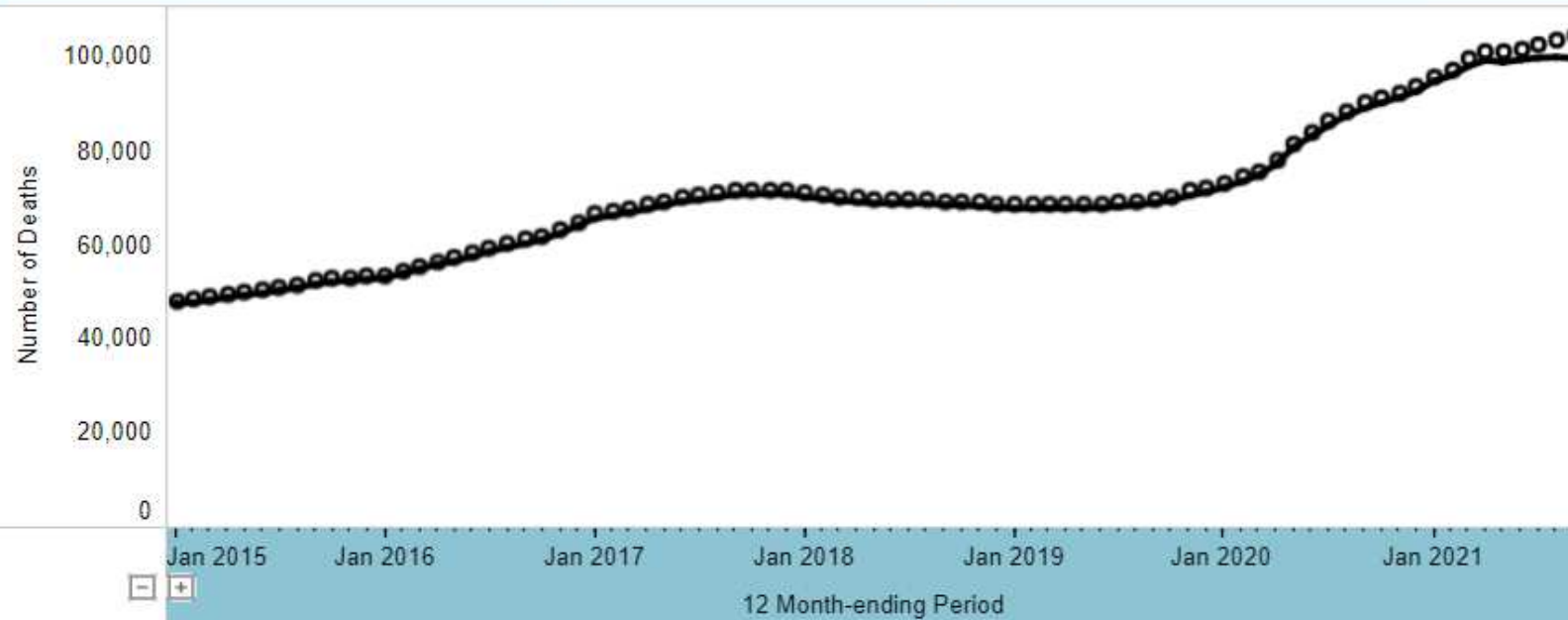
- Lung (17.4%)
- Colorectal (12.0%)
- Breast (9.0%)
- Prostate (5.8%)

Declines were observed in all age groups, including children and adolescents aged younger than 18 years.

12 MONTH PROVISIONAL NUMBER OF OVERDOSE DEATHS

Based on data available for analysis on: **2/6/2022**

Figure 1a. 12 Month-ending Provisional Counts of Drug Overdose Deaths: United States



**>104,000
Drug Overdose
Deaths**

**For 12 months ending
in September 2021**

CHILDREN'S HEALTH

Pediatricians say the mental health crisis among kids has become a national emergency

October 20, 2021 · 3:50 PM ET

COVID school closures most harm students from poorest neighborhoods

National Bureau of Economic Research model predicts that one year of school closures will cost ninth graders in the poorest communities a 25% decrease in their post-educational earning potential, even if it is followed by three years of normal schooling.





**THE COVID-19 PANDEMIC HAS
CATALYZED INNOVATION AND CHARTED
THE COURSE FOR CONTINUED HEALTH
CARE REFORM**

Vaccines

>10 billion doses administered and counting...



THE FACTS: OPERATION WARP SPEED (By Jan 20, 2021)

- 2 vaccines authorized and another imminent, in less than one year:
- 900 million doses procured and option contracts for another 2 billion doses
- >1 billion needles and syringes procured and engaged McKesson to package all needed supplies
- Utilized the DPA 18 times to assure raw materials and equipment
- Contracted 19 pharmacy chains with over 40,000 sites to administer vaccine
- >70,000 total vaccination sites qualified and prepared
- PREP administer vaccinations
- On January 20, 1.5 million doses of vaccine were delivered into arms

Monoclonal Antibodies and Next-Gen Antibodies



US MARKETS ▲ GSK \$42.68 +1.49 3.62%

GSK's COVID-related sales close to \$2 bln, profit boost to wane in 2022

HEALTH AFFAIRS FOREFRONT

RELATED TOPICS:

COVID-19 | ACCESS TO CARE | VACCINES | DISEASES | TECHNOLOGY | PHARMACEUTICALS | PANDEMICS

Monoclonal Antibodies For COVID-19 Are A Potentially Life-Saving Therapy: How Can We Make Them More Accessible?

January 25, 2022 07:00 AM EST | Financing



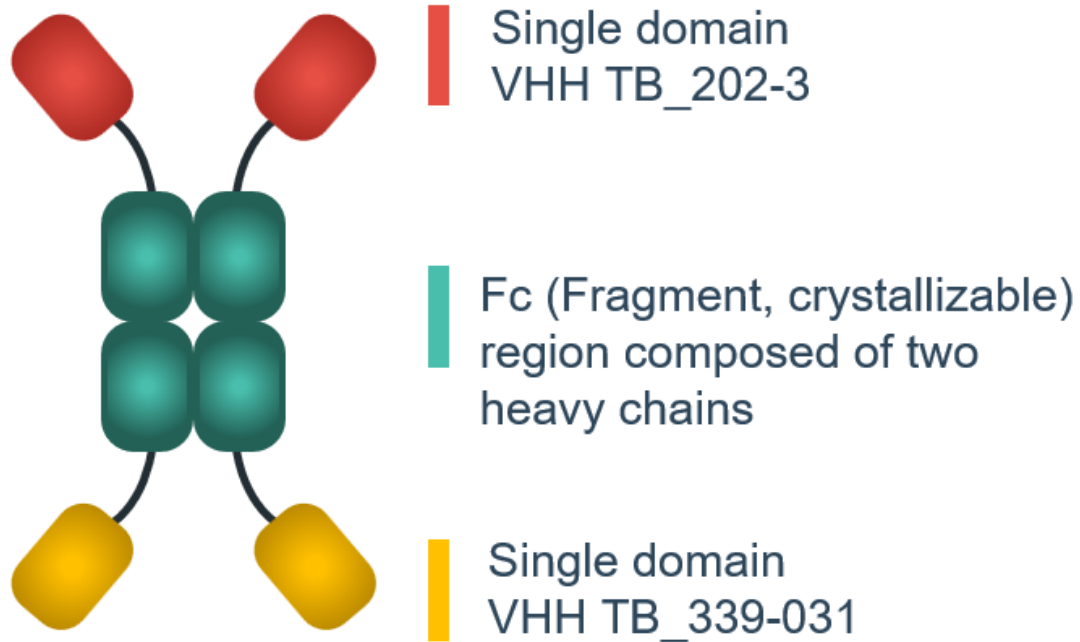
Nasal sprays to stave off viruses days at a time? J&J's newest biotech partner draws \$140M for 'proactive' approach



Amber Tong
Senior Editor

Next Generation Antibodies and Nanobodies: Potent, Less Expensive, Scalable, Opens Door to New Indications

RBT-0813



**BISPECIFIC CONSTRUCT OPTIMIZED
FROM SINGLE DOMAIN VHH ANTIBODIES**



TESTING AND HOME DIAGNOSTICS OPEN NEW PARADIGM



You can't test your way out of a pandemic, but....

POLITICO

March 11-13, 2020

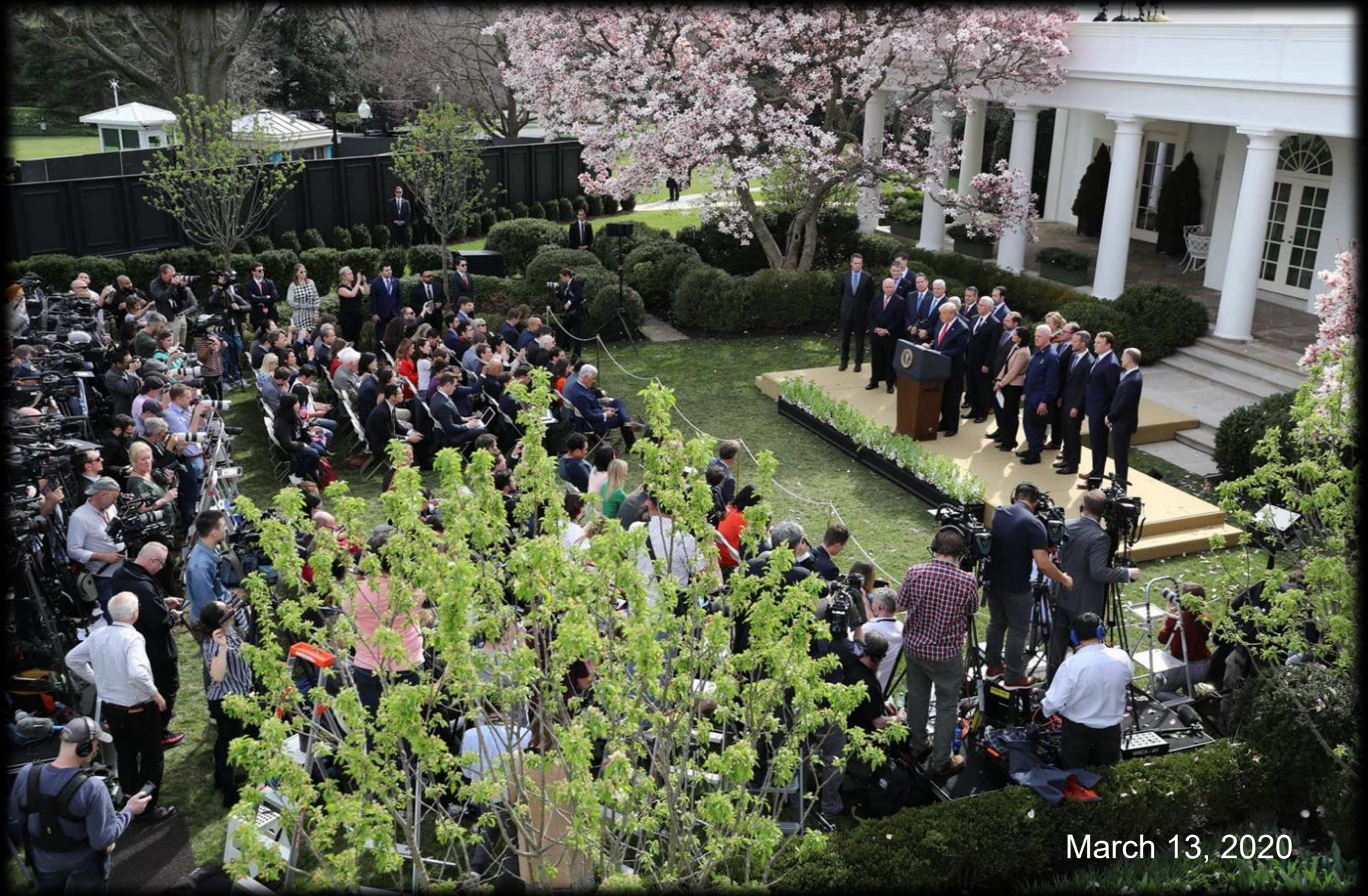


CORONAVIRUS

Trump administration rolls out new coronavirus push, names HHS testing czar

“The changes have been made and testing will soon happen on a very large scale basis,” Trump said in a pair of tweets Friday morning.





March 13, 2020

CORONAVIRUS TESTING

New Options for Consumers

SCREENING WEBSITE
Log-in And Symptom
Screening Tool

NO
No Symptoms

YES
Symptoms

"DRIVE THRU"
Testing Clinics

LABS
Tests Shipped to Labs

RESULTS
Displayed on
Screening Website



The “Obama Playbook” mentions testing only once in its 69 pages:

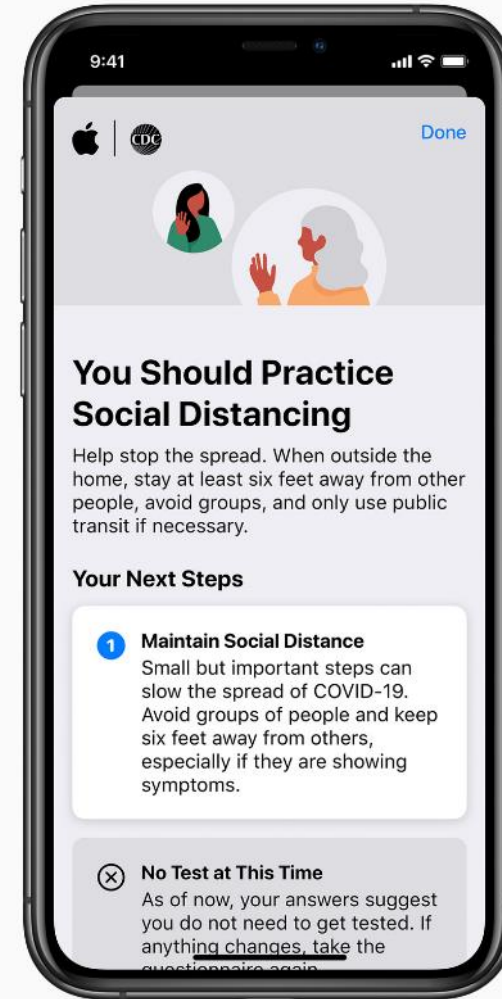
“FDA can provide assistance by working closely with manufacturers and US government partners to expedite the development and availability of biologics (including vaccines), drugs, and devices (including diagnostic tests and personal protective equipment).”



March 15, 2020

UPDATE
March 27, 2020

Apple releases new COVID-19 app and website based on CDC guidance



COVID-19 U.S. Testing Strategy

Results by the Numbers

January 13, 2021



>264 million
Tests Completed

>170 million
Test Capacity January



\$30 billion
to states, territories
and tribes for **TESTING***

* includes 2021 supplemental

\$20 billion
to nursing homes for
testing and other needs

>\$1.28 billion
testing reimbursement for
uninsured (HRSA)

Critical Supplies Delivered to States

191 million swabs
229 million tubes of transport media
4.3 million ID NOW molecular tests

Point-of-Care Instruments to Nursing Homes



15,300 nursing homes received point-of-care instruments AND

5.3 million point-of-care tests

BinaxNOW Rapid Antigen Tests



- **94.4 million** distributed to states
- **54.4 million** distributed to nursing homes, assisted living, HBCUs, tribes and disaster relief

K-12 School Pilot Program

120,000 Tests

- Louisville
- Los Angeles
- New Orleans
- Tulsa
- Rhode Island
- District of Columbia



Strategic Surveillance Program

>1.8 million tests

- Pennsylvania (School Pilot)
- Washington (School Pilot)
- Colorado
- North Dakota
- Rhode Island
- Utah
- Veterans Affairs
- Select Tribal Nations



COVID-19 U.S. Testing Strategy

Results by the Numbers

January 13, 2021



Testing: Research and Development

> **\$310 million**
for rapid antigen tests

> **\$582 million**
for lab based tests

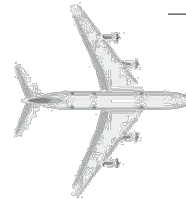
> **\$195 million**
for rapid molecular tests

> **\$107 million**
for novel diagnostics



Building Infrastructure: DPA and other Investments

13 DPA Rated Orders



42 Air Bridge Flights
for testing supplies:
swabs, pipette tips, others



309 EUAs for Tests

issued by FDA -- including 3 at-home tests and 32 home collections

\$265.3 million

to increase U.S. swab production

\$180.2 million

to increase U.S. reagents/kits production

\$53 million

to increase U.S. pipette tip production

Federally Enabled Testing Sites

>**1,300** Federally Qualified
Health Centers



>**7,600** Retail and community sites

>**644** Surge testing sites
in 23 states



Acquisition of Products and Services

\$1.4 billion
Community Based Testing Sites

\$481 million
CUE Rapid Molecular Tests

\$133 million
BD and Quidel Rapid Tests

\$915 million
BinaxNOW Rapid Tests

\$583 million
Health Center Testing Capacity

\$659 million
Swab and Media Procurement

\$198 million
ID NOW Rapid Molecular Tests

\$30 million
Diagnostics Data Platform



\$50 million
National Wastewater
Surveillance System

\$400+ million
Solicitation for Home Test
Capacity (pending)

TESTING AND HOME DIAGNOSTICS OPEN NEW PARADIGM



THE CRITICAL IMPORTANCE OF ORAL ANTI-VIRAL MEDICATIONS

ars TECHNICA

ASGARDIAN MEDS — Meet molnupiravir, Merck's Thor-inspired pill that hammers COVID

In Phase III trial, the drug smashed hospitalization and death rate by about half.

BETH MOLE · 10/1/2021, 1:04 PM



Molnupiravir sales were \$952 million in the Q4 2021; expect another \$5 - \$6 billion in sales in 2022

COVID-19 pill Paxlovid could add \$15B-\$22B to Pfizer 2022 revenue - Barclays

Nov. 17, 2021 9:16 AM ET | Pfizer Inc. (PFE) | MRK | By: Jonathan Block, SA News Editor |



ORAL ANTIVIRAL MEDICATIONS WILL EXPAND FOR OTHER DISEASES

Altesa BioSciences

Developing Drugs to Treat Respiratory Viruses and Global Viral Threats



Our Science

RNA VIRUSES

The prevalent cause of
severe human viral
diseases.

The COVID Public Health Emergency
Accelerated distributed delivery of health care:

***How do we further extend democratization of
health care emphasizing prevention?***

TELEHEALTH – TIME TO PUSH THE LIMITS

- During the pandemic, HHS utilized 387 temporary regulatory flexibilities made possible by the Public Health Emergency Declaration
- 45 of the 387 related to Telehealth
 - 35 from CMS (Waiver, IFR, Guidance)
 - 8 FDA (Guidance)
 - 1 ACF (Waiver)
 - 1 OCR (Other Regulatory Action)

- **> 30% of Community Health Center Visits Occurred by Telehealth**
- **> 81% of Medicare beneficiaries were offered telehealth services during the COVID-19 pandemic**

FURTHER DEMOCRATIZATION OF HEALTH CARE: LEVERAGING PHARMACISTS AS FRONT-LINE HEALTH PROVIDERS: *PREP ACT ACTIONS (2020)*

- **April 8:** Pharmacists and COVID-19 Testing
- **August 19:** Pharmacists/Pharmacy Interns and Childhood Vaccines
- **August 31:** COVID-19 Screening Tests at Nursing Homes, Assisted-Living Facilities, Long-Term-Care Facilities, and other Congregate Facilities*
- **Sept 3:** Pharmacists/Pharmacy Interns and COVID-19 Vaccines
- **October 20:** Pharmacy Technicians and Childhood Vaccines, COVID-19 Vaccines, and COVID-19 Testing
- **October 29:** Pharmacies Distributing and Administering Certain Covered Countermeasures are Covered Entities

ENABLE PHARMACISTS TO SCREEN FOR HIV AND INITIATE PREP or ANTI-VIRAL TREATMENT

- 1 in 2 people with HIV have the virus at least 3 years before diagnosis
- 1 in 4 people with HIV have the virus at least 7 years before diagnosis
- 1 in 5 people with HIV are diagnosed with advanced disease (AIDS)
- 7 in 10 people with HIV saw a healthcare provider in the 12 months prior to diagnosis and failed to be diagnosed

80% of new HIV infections are transmitted from people who don't know they have HIV or are not retained in treatment

EARLY DETECTION OF CHRONIC KIDNEY DISEASE

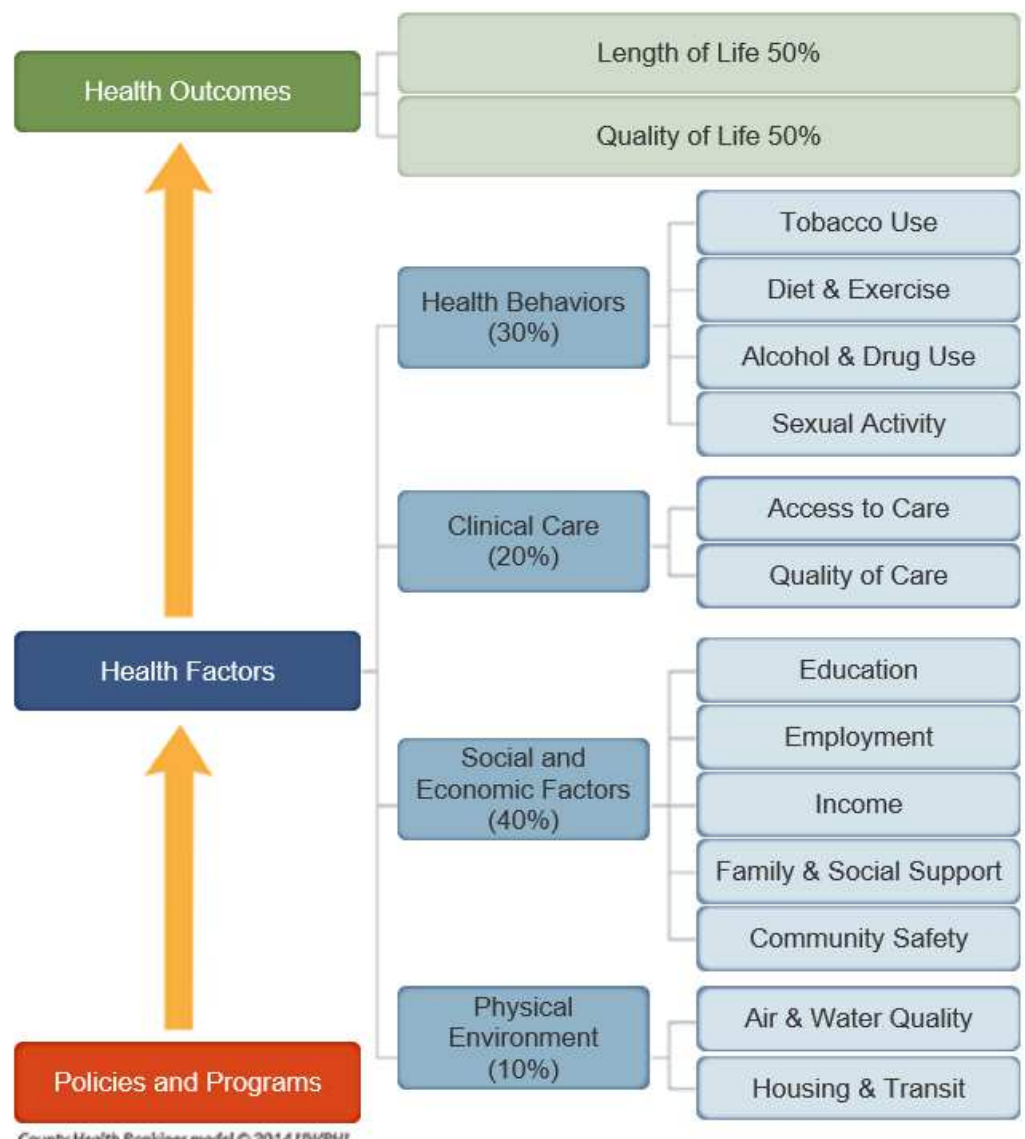
If all Americans at risk for chronic kidney disease received proper screening and were placed on pharmaceutical therapy (SLGT2 inhibitors)...

**The US would save at least 150,000 lives per year
and prevent at least 375,000 cases of significant
CKD progression every year**

In 2018, Medicare beneficiaries with CKD cost over \$81.8 billion,
and treating people with ESRD cost an additional \$36.6 billion
(excluding drug costs)

**The US cannot fix our poor health
and historic health disparities
with a few supplemental appropriations**

HEALTH OUTCOMES FRAMEWORK (RWJF)



WHY HEALTH OUTCOMES SHOULD IMPROVE:

Focus on Prevention and Value Based Payments



Secretary Alex M. Azar II

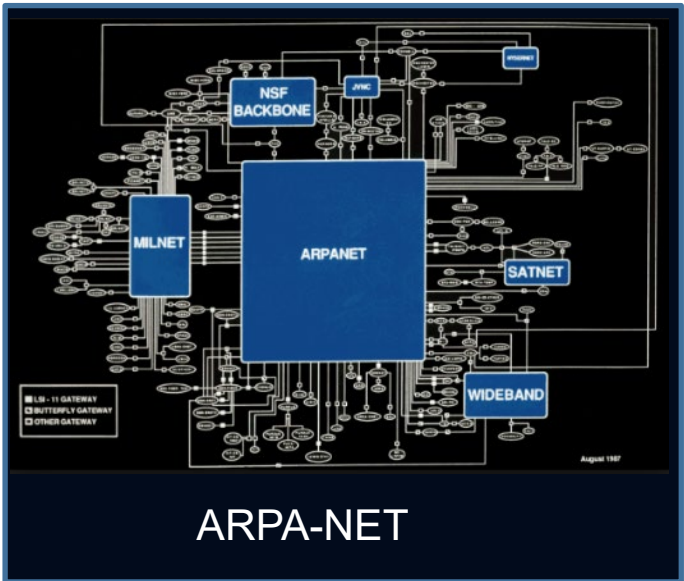
“What we want from our system is better health; therefore, what we should pay for in our healthcare system is better health.”

Of the priorities I have picked for HHS, the most ambitious and furthest reaching, is transforming our healthcare system into one that pays for health and wellness rather than sickness and procedures.

**THE US WILL ENHANCE OUR
INNOVATAION ECOSYSTEM**

ARPA-H

DARPA MODEL OF DISRUPTIVE INNOVATION



Cite as: F. S. Collins *et al.*, *Science*
10.1126/science.abj8547 (2021).

ARPA-H: Accelerating biomedical breakthroughs

Francis S. Collins¹, Tara A. Schwetz^{1,2}, Lawrence A. Tabak¹, Eric S. Lander²

¹National Institutes of Health; Bethesda, MD 20892, USA. ²Office of Science and Technology Policy, Executive Office of the President; Washington, DC 20502, USA.
Email: eric.s.lander@ostp.eop.gov

A DARPA-like culture at NIH can drive biomedical and health advances

HEARING ON "ARPA-H: THE NEXT FRONTIER OF BIOMEDICAL RESEARCH"

Date: Tuesday, February 8, 2022 - 10:30am

Location:

Hybrid Hearing in the John D. Dingell Room, 2123 of the Rayburn House Office Building, and Cisco Webex

Subcommittees: 117th Congress
Health (117th Congress)

POLITICS

STAT+

San Francisco, Austin, or Raleigh? White House contemplates an out-of-D.C. address for new biomedical research agency



By [Lev Facher](#)  July 20, 2021

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