

Life Science Caucus Meeting
February 22, 2021
8:00am

Co-chairs:
Senators Newton and Woodard
Representatives White and Reives

Meeting will begin shortly



Agenda

- Welcoming Remarks by Chairs
 - Senators Paul Newton and Mike Woodard
 - Representatives Donna White and Robert Reives
- Presentation – BIO – Phyllis Arthur
- Presentation – PhRMA – Thomas Hardaway
Zach Poss
- Presentation – NCBI – Laura Gunter
- Discussion
- Adjourn

NC Life Science Industry Background

- NC Biotechnology Center – founded 1984
 - Targeted funding for university research and faculty recruitment
 - Early-stage funding for life science technology companies
 - K-12 educational outreach previously
 - State marketing/recruiting efforts in conjunction with NC Commerce Dept/EDPNC
- NC BIO – established 1994
 - Trade association
 - Member supported
 - Policy efforts to support industry
 - Innovation economy
 - Training facilities
 - Work with federal partners: BIO, PhRMA, AdvaMed, MDMA, ACRO



Phyllis Arthur is Vice President for Infectious Diseases and Diagnostics Policy at the Biotechnology Innovation Organization (BIO). In this role Ms. Arthur is responsible for working with member companies in vaccines, antimicrobial resistance, molecular diagnostics and biodefense on policy, legislative and regulatory issues.

Ms. Arthur joined BIO in July 2009 as the Director of Healthcare Regulatory Affairs. Prior to joining BIO, she worked in numerous marketing and sales positions for Merck & Co Inc in their Vaccine Division. Over her 16-year career in vaccines, Ms. Arthur launched several exciting new vaccines in the United States and internationally, including the first HPV vaccine, GARDASIL. During her years in Marketing, she worked closely with clinical and academic thought leaders in infectious diseases, oncology and public health. In addition, Ms. Arthur also led a large vaccine sales organization of over 75 representatives and managers covering 14 states.

Before graduate school, Ms. Arthur worked as a research assistant for two economists at the Brookings Institution in Washington, DC. There she conducted economic analyses related to savings and investment policies for the OECD countries.

Ms. Arthur received her B.A. in 1987 in Economics and International Politics from Goucher College and her M.B.A. in 1991 from the Wharton School of Business at the University of Pennsylvania.





Thomas Hardaway is a Senior Regional Director for the Pharmaceutical Research and Manufacturers of America (PhRMA). He has primary responsibility for managing State Government Affairs in North Carolina, Georgia, Tennessee and South Carolina in a manner consistent with the priorities of PhRMA and the State Advocacy Department. He develops, manages and executes the policy agenda for State Government Affairs in conjunction with Alliance Development and Communications efforts and develops and implements strategies to impact state-level legislation. He is also responsible for developing and delivering policy statements, talking points and testimony related to industry legislation and regulation, as well as provide counsel to other PhRMA staff and taskforce members concerning PhRMA policy issues. He also represents PhRMA at various public meetings, legislative hearings on the state level and regulatory agency meetings.

He is based in Atlanta, Georgia where he has lived since moving from North Carolina in 2000. Prior to joining PhRMA, he practiced law and served several terms in the North Carolina House of Representatives representing the 7th House District in 1987, 1989, 1991, 1997, and 1999.



Zach Poss is Director of State Policy for PhRMA. In his tenure, he has worked with states on a wide-range of health policy issues throughout the Southeast and Midwest. Prior to working at PhRMA, Zach interned with Senator Lamar Alexander, then chair of the Senate HELP Committee. Zach is a proud graduate of the American University, where he earned his Bachelor of Arts in Political Science and George Washington University, where he earned his Master of Public Policy.

Industry's Response to the COVID-19 Pandemic

Phyllis Arthur

Vice President, Infectious Diseases & Diagnostics Policy

Biotechnology Innovation Organization

February 2021



About BIO

Founded	1993
Tax Status	Non-profit trade association
CEO	Michelle McMurry-Heath, MD, PhD
Headquarters	Washington, DC
Staff	~160
Members	~1,000

BIO's Mission is to advance biotechnology innovation by promoting sound public policy and fostering collaboration, both locally and globally.

Diverse membership

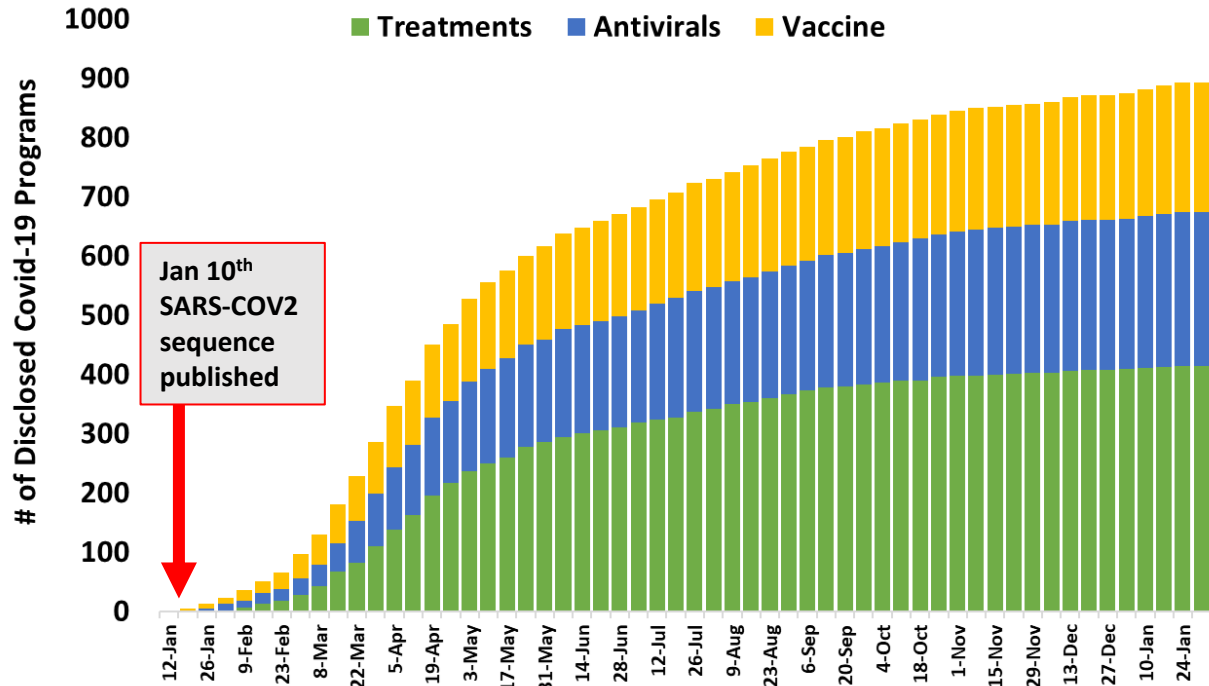
- Innovative technologies focused on human health, agriculture, and environment
- Start-ups to Fortune 500 companies with international membership
- Universities, research institutes, investors
- Council of State Biosciences Associations (CSBA) – state affiliates
- International Council of Biotech Associations (ICBA) – international affiliates

Timing of Response by Industry

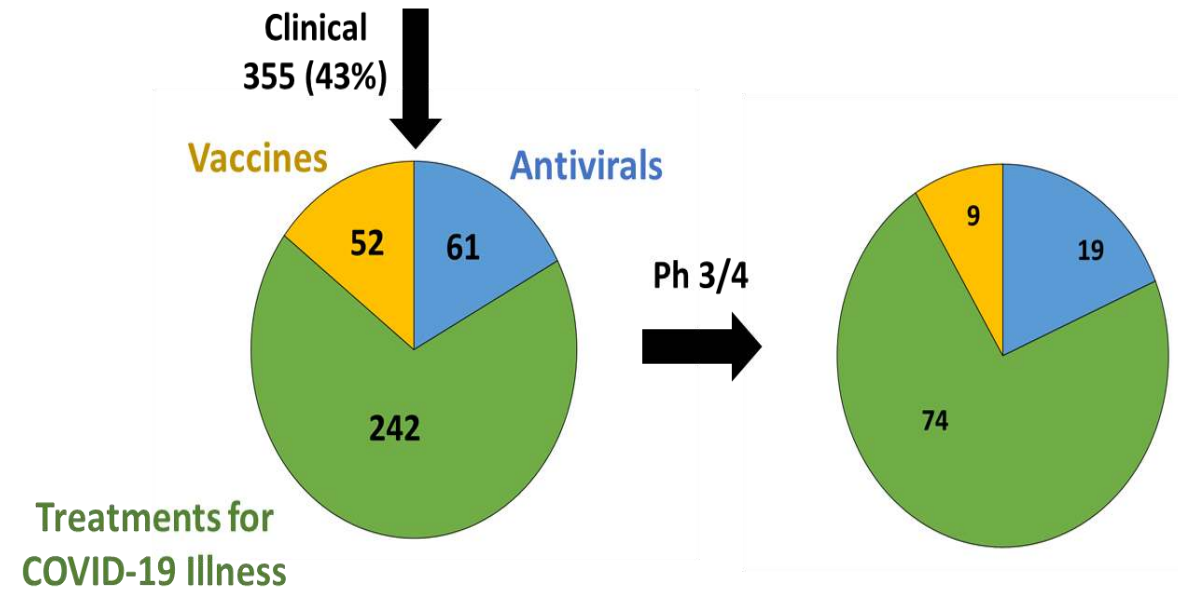
894 unique drug programs launched in 13 months

72% originated in Small Companies

51% originated in US



Week of first press release announcing program



Weekly pipeline updates:

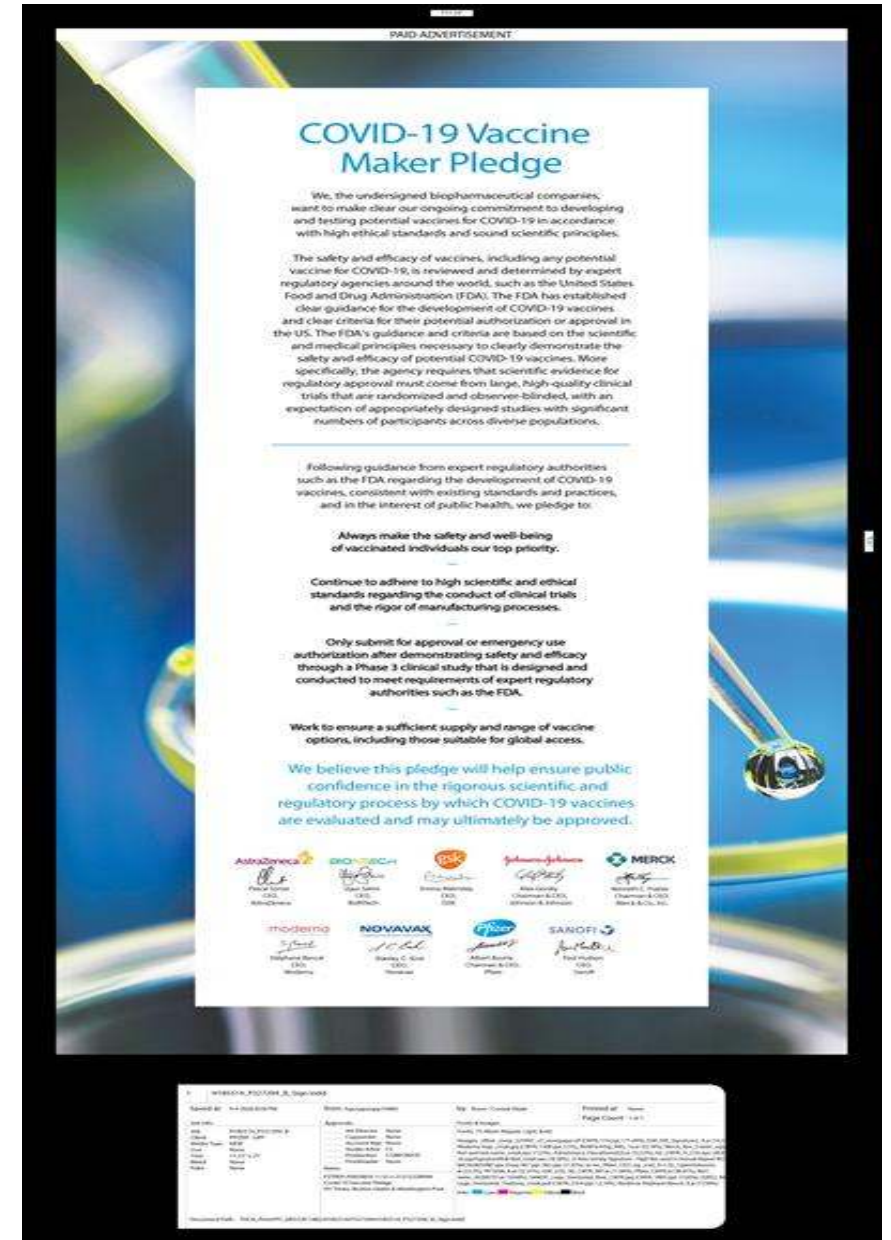
www.bio.org/covidpipelinetracker

Updated Feb 8, 2021

Biomedtracker, Biocentury, BIO Industry Analysis

Industry Commitment to Scientific Rigor, Transparency and Diversity


- September 8, 2020
- Nine vaccine company CEOs pledged to uphold scientific and ethical standards
- Pledged to “always make the safety and well-being of vaccinated individuals our top priority.”
- “Together these nine companies have collectively developed more than 70 novel vaccines that have helped to eradicate some of the world’s most complex and deadly public health threats”



<https://www.cnn.com/2020/09/08/health/covid-19-vaccine-pharmaceutical-companies-pledge-bn/index.html>

Clinical & Preclinical Stage Vaccine Pipeline

 BARDA / DoD funding

 OWS funded

 Jointly developed



Source: Biomedtracker, Biocentury, BIO Industry Analysis

1. PrEP Biopharm vaccine dsRNA, all others mRNA

Oxford, Astrazeneca: ChAdOx1. Symvivo: bacTRL-Spike. Baylor College: BCG tuberculosis vaccine.

Sinopharm with two vaccines in phase 1 trials (one beginning Apr 12 the other Apr 27)

Info as of Feb 21, 2021, not exhaustive

COVID-19 Vaccines in Development for SARS-CoV2

Company/ Candidate	Vaccine type	Product characteristics	Trial characteristics	Recruiting status
Pfizer / BioNTech	mRNA	2 doses (0, 21 days) IM -70 degrees C	44,000 12-85 years of age	EUA authorized Dec 11, 2020
Moderna	mRNA	2 doses (0, 28 days) IM -20 degrees C	30,000 18-55, 56+	EUA authorized Dec 17, 2020
Johnson & Johnson	Viral vector (non-replicating)	1 dose / (separate 2 dose trial) IM 2-8 degrees C	60,000 / 30,000 (US) 18-55, 65+	FDA meeting Feb 26, 2021
AstraZeneca / Oxford	Viral vector (non-replicating)	2 doses (0, 28 days) IM 2-8 degrees C	30,000 18+	Phase 3 completed
Novavax	Recombinant Protein subunit	2 doses (0, 21 days) IM 2-8 degrees C	30,000 18+	Phase 3 enrollment completed
Sanofi Pasteur / GSK	Recombinant Protein subunit	1 or 2 doses IM 2-8 degrees C		Phase 2 enrollment completed
Inovio	DNA	2 doses (1, 28 days) ID w device 2-8 degrees C		Completed
Medicago	Recombinant Protein subunit	2 doses (0, 21 days) IM 2-8 degrees C		Phase 2 enrollment complete

The Speed of COVID-19 Vaccine Development

- Unprecedented pace of development without sacrificing efficacy and safety
- Clinical trials were actually larger than with other vaccines (30,000 -40,000 people)
- Building a House:
 - Existing Foundations
 - Years of research on other viruses
 - New technology
 - Leverage new science to develop vaccines – no need for the virus to grow
 - Strong collaboration
 - FDA, companies, doctors all working to do more together
 - Extra and prioritized resources
 - Companies moved staff to COVID from all other projects



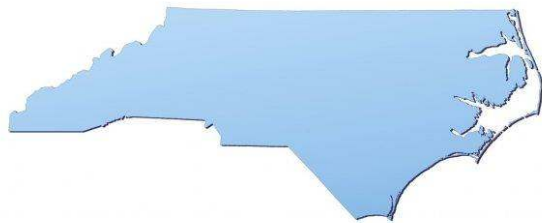
Vaccinations are increasing across the country

COVID-19 Vaccinations in the United States

Overall US COVID-19 Vaccine Delivery and Administration; Maps, charts, and data provided by the CDC, updated daily by 8 pm ET[†]

Total Doses Delivered	Total Doses Administered	Number of People Receiving 1 or More Doses	Number of People Receiving 2 Doses
75,204,965	63,090,634	43,628,092	18,865,319

CDC | Data as of: Feb 21 2021 6:00am ET | Posted: Feb 21 2021 12:25PM ET



North Carolina

Total Delivered: 2,363,200 (22,532 per 100k)
Total Doses Administered: 2,068,505 (19,722 per 100k)
People Receiving 1 or More Doses: 1,373,952 (13,100 per 100k)
People Receiving 2 Doses: 691,447 (6,593 per 100k)

www.covidvaccinefacts.org launched by BIO in December 2020

The screenshot shows a web browser window displaying the homepage of www.covidvaccinefacts.org. The browser's address bar shows the URL and several tabs are open, including 'National Influenza...', 'Pandora Radio - Lis...', 'The Affordable Car...', 'Washington, DC Re...', 'nextbus22 & 82min', 'path Global progra...', and 'Imported From IE'. The website header features the title 'COVID VACCINE FACTS' in green and yellow, with navigation links for 'Home', 'FAQs', and 'About', and a language dropdown set to 'EN'. A large hero image of a smiling family is in the background. A central text box reads 'Find answers to your questions about COVID-19 vaccines.' Below this is a search bar containing the text 'Try "What is a vaccine?"' and a blue 'Search' button. At the bottom, a 'Top Questions' section features three colored buttons with right-pointing arrows: a teal button for 'What is a vaccine?', an orange button for 'How are vaccines developed?', and a purple button for 'How will we know a Covid-19 vaccine is safe and...'. The Windows taskbar at the bottom shows the search bar and various application icons, with the system clock indicating 9:56 PM on 1/13/2021.



Value of Biopharmaceutical Industry

Thomas Hardaway and Zachary Poss

North Carolina Life Science Caucus

PhARMA
RESEARCH • PROGRESS • HOPE

Biopharmaceutical Sector Supported Jobs in North Carolina

44,969

Direct Sector Jobs



206,084

Jobs Supported in
Other Sectors



251,053

Total Jobs

Biopharmaceutical Sector's Contribution to North Carolina's Economy



ECONOMIC OUTPUT

\$74.5B

Total Value of Goods and Services
Supported by Biopharmaceutical Sector



REVENUE GENERATED

\$3.6B

Total State and Federal Taxes Paid



EMPLOYEE PRODUCTIVITY

\$871,287

Per Employee in Direct
Biopharmaceutical Sector Jobs

VERSUS

\$164,864

Per Employee Across All
North Carolina Jobs



AVERAGE COMPENSATION

\$115,605

Per Employee in Direct
Biopharmaceutical Sector Jobs

VERSUS

\$54,182

Per Employee Across All
North Carolina Jobs



Our Commitment to *Beat* Coronavirus

We are **rapidly screening our vast global libraries of medicines** to identify potential treatments and have numerous clinical trials underway to test new and existing therapies

We are **dedicating our top scientists and using our investments in new technologies** to speed the development of safe and effective vaccines

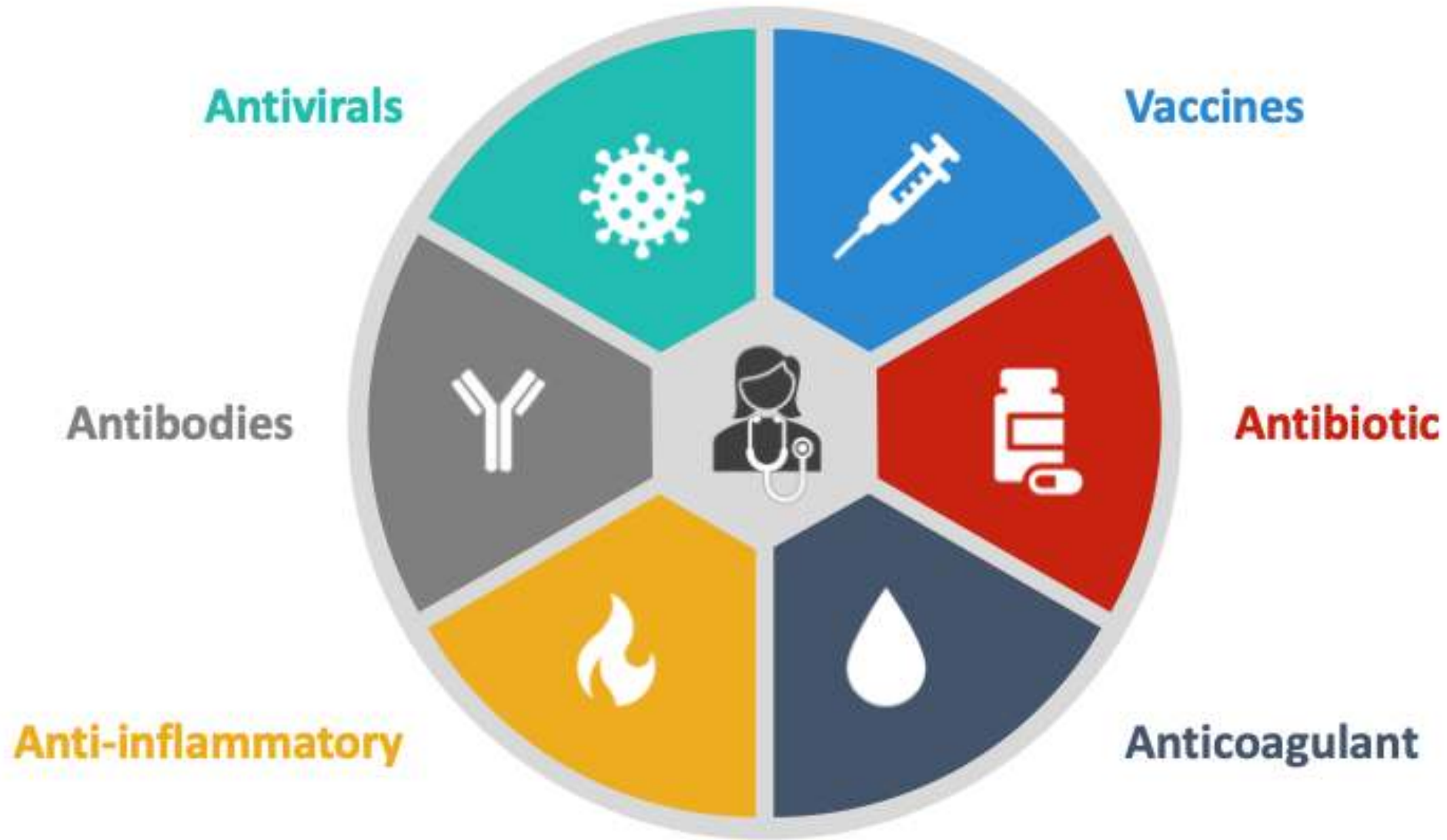
We are **sharing the learnings from clinical trials in real time** with governments and other companies to advance the development of additional therapies

We are **expanding our unique manufacturing capabilities and sharing available capacity** to ramp up production once a successful medicine or vaccine is developed

We are **collaborating with government agencies, hospitals, doctors and others** to donate supplies and medicines to help those affected around the world

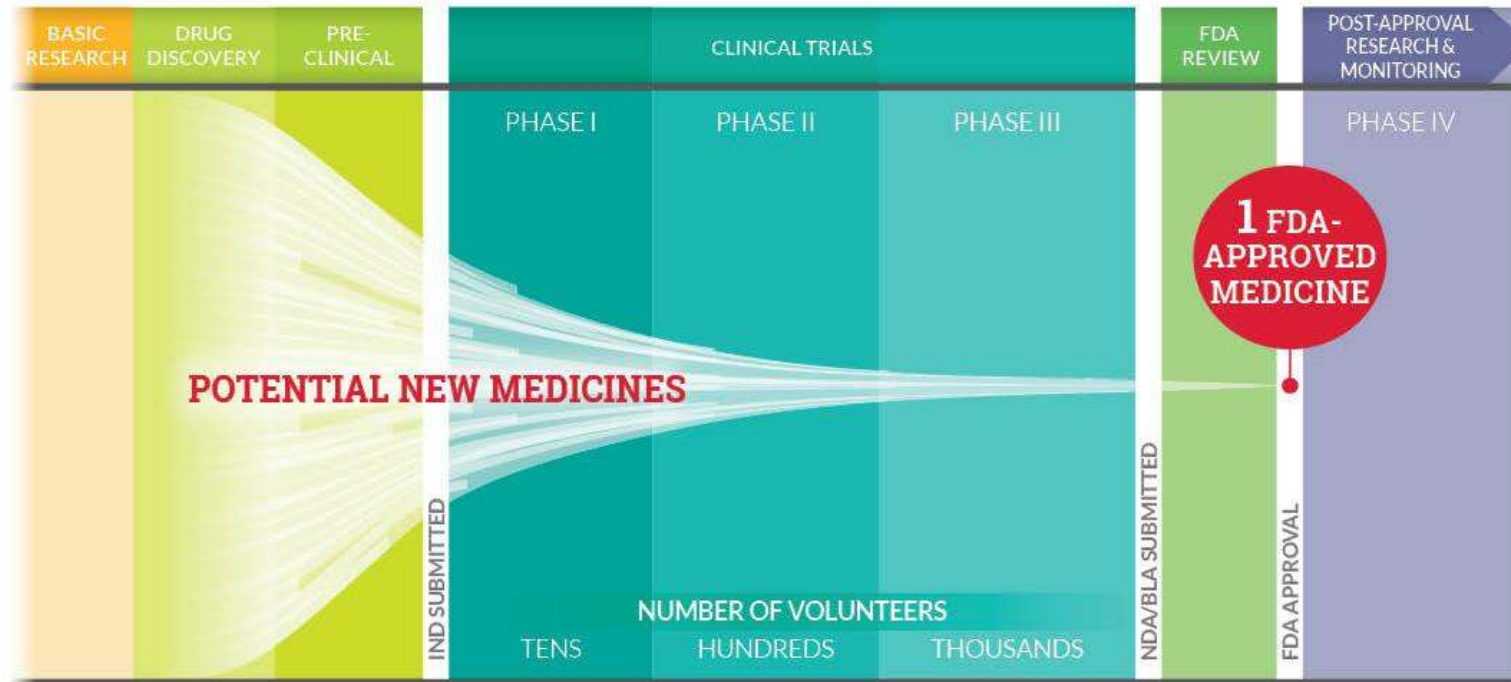
We are **working with governments and insurers** to ensure that when new treatments and vaccines are approved they will be available and affordable for patients

COVID-19 Treatments and Vaccines



The R&D Process for New Drugs Is Lengthy and Costly, With High Risk of Failure

From drug discovery through FDA approval, developing a new medicine takes, on average, 10 to 15 years and costs \$2.6 billion.* Less than 12% of the candidate medicines that make it into Phase I clinical trials are approved by the FDA.



Key: IND=Investigational new drug application, NDA=New drug application, BLA=Biologics license application

*The average R&D cost required to bring a new FDA-approved medicine to patients is estimated to be \$2.6 billion over the past decade (in 2013 dollars), including the cost of the many potential medicines that do not make it through to FDA approval.

The Costs of Drug Development Have More Than Doubled Over the Last 30 Years

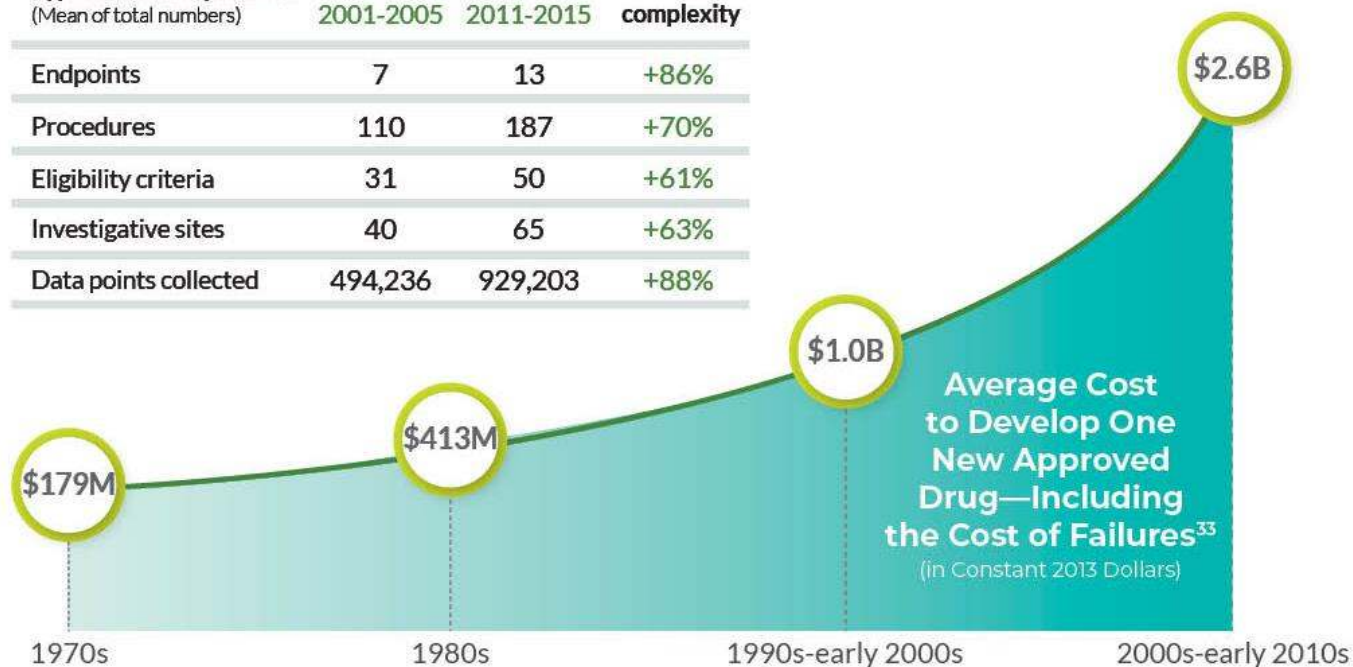
Many factors are driving up the costs of biopharmaceutical R&D, including increased clinical trial complexity, larger clinical trial sizes, more data sources to integrate, greater focus on targeting chronic and degenerative diseases, and higher failure rates for drugs tested in earlier-phase clinical studies.³³



A growing number of pharmaceutical and biotechnology companies . . . have taken steps to optimize their protocol designs in order to improve feasibility, ease site and subject participation burden, . . . and gather more meaningful clinical data.”

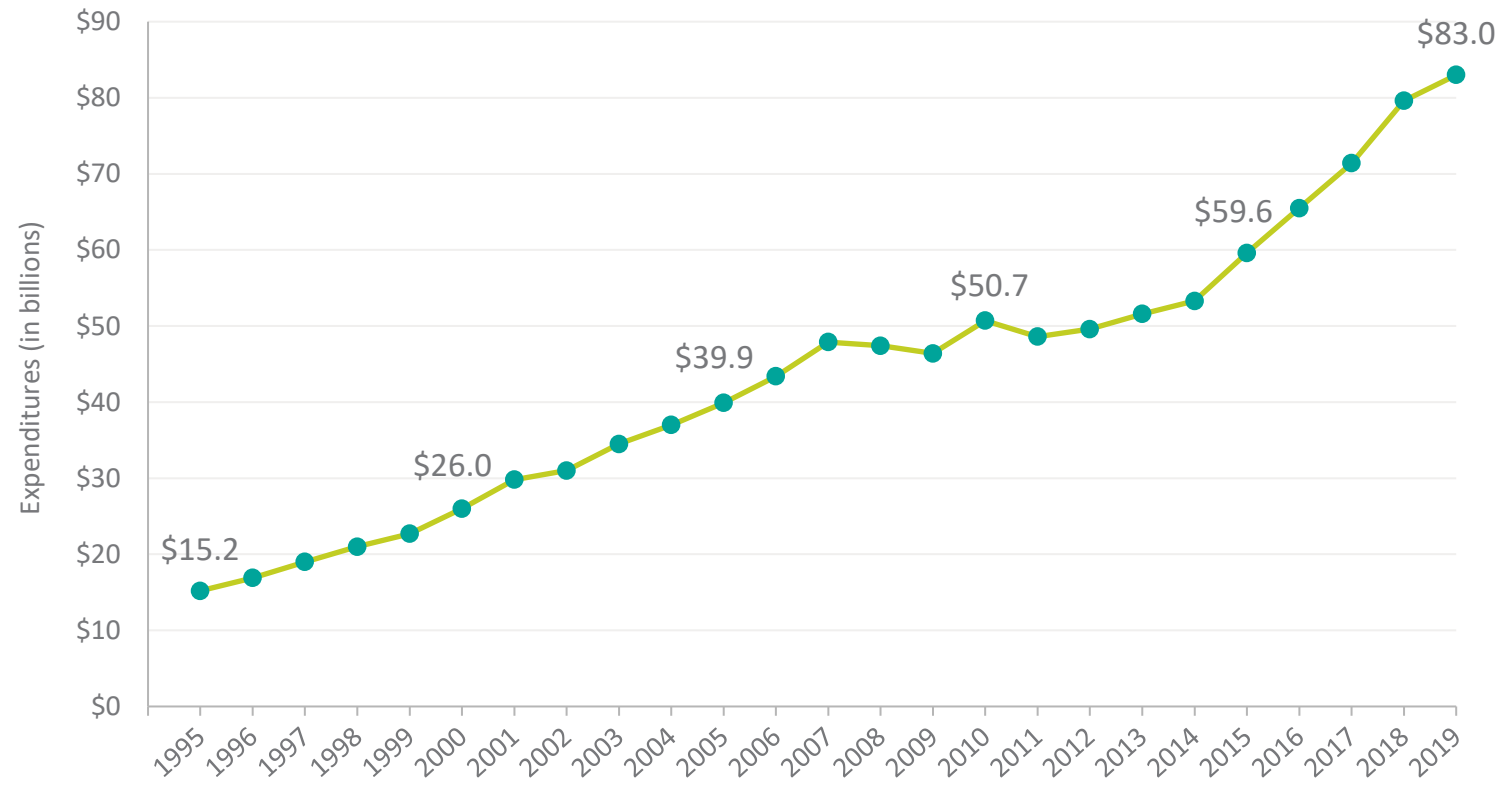
Ken Getz, MBA, Tufts Center for the Study of Drug Development, and Rafael Campo, Medidata Solutions³⁴

Typical Phase III protocol ³⁵ (Mean of total numbers)	2001-2005	2011-2015	Increase in complexity
Endpoints	7	13	+86%
Procedures	110	187	+70%
Eligibility criteria	31	50	+61%
Investigative sites	40	65	+63%
Data points collected	494,236	929,203	+88%



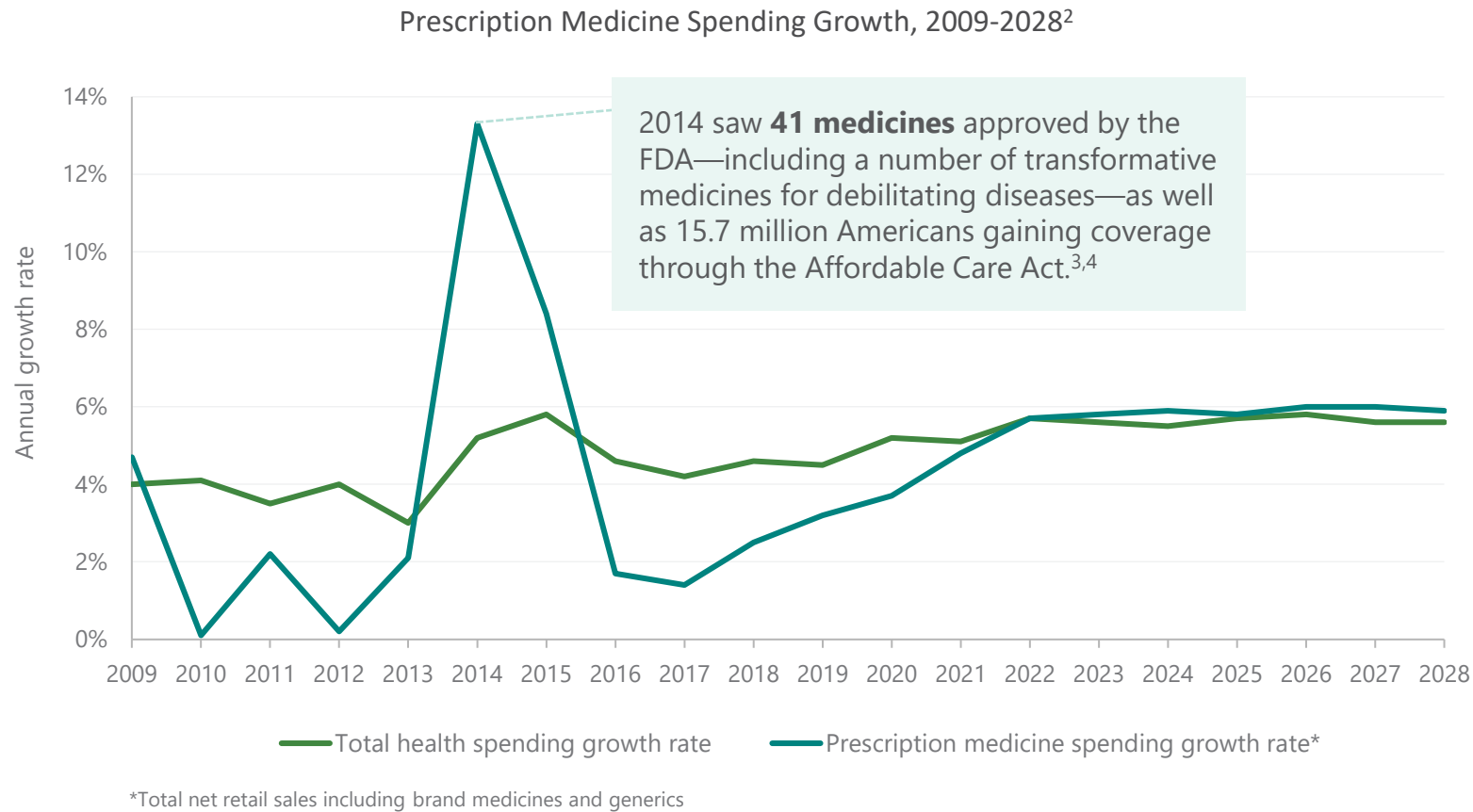
PhRMA Member Company R&D Investment

PhRMA Member Company R&D Expenditures, 1995-2019

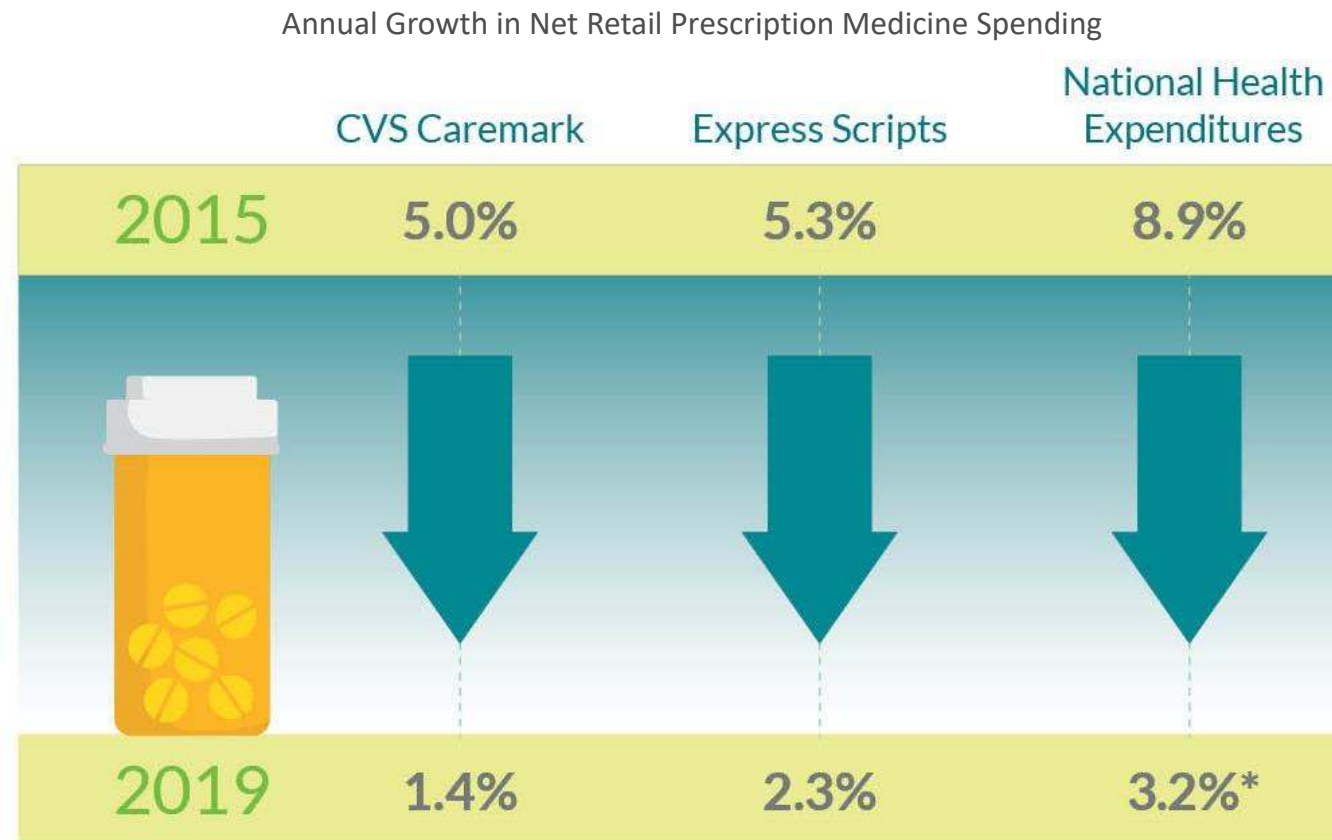


In 7 of the Last 10 Years, Retail Prescription Medicine Costs Grew More Slowly Than Total Health Care Costs

Government actuaries project prescription medicine spending growth to remain between 3% and 6% annually through 2028, in line with overall health care spending growth.¹



Pharmacy Benefit Managers (PBMs) and Government Actuaries Report Slowing Growth in Medicine Spending



*Projected

Manufacturer Cost Sharing Assistance Can Help Patients Pay Their Out-of-Pocket Costs

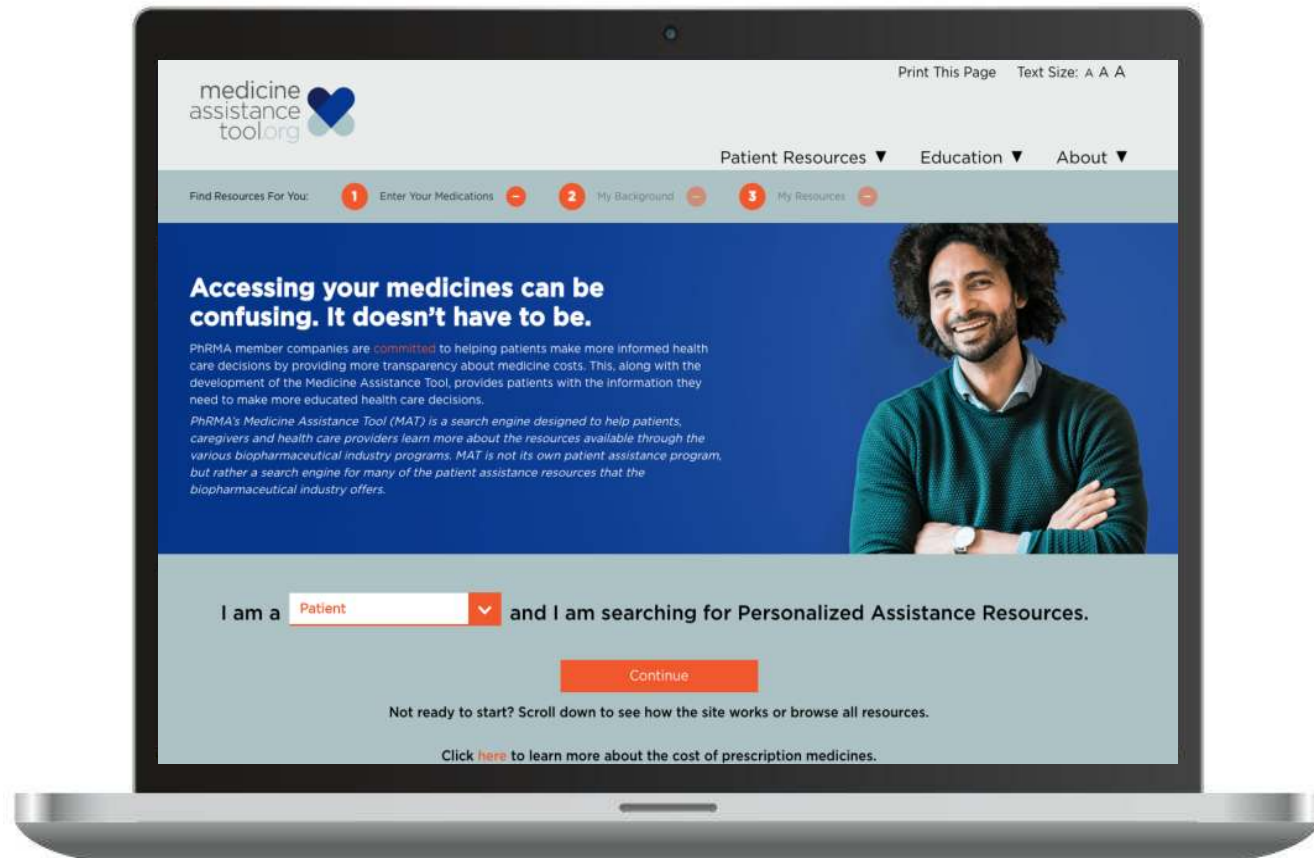


In 2017, just **0.4%** of commercial claims were filled with a coupon for a **brand medicine** that had a generic equivalent.

Programs that do not count manufacturer cost sharing assistance toward a patient's deductible or out-of-pocket maximum hurt the sickest patients, leaving them vulnerable to unexpected out-of-pocket costs as high as **several thousands of dollars** to continue taking their medicine.



Many of America's Biopharmaceutical Companies Are Expanding Their Assistance Programs To Help More People



950+

public and private programs

The Medicine Assistance Tool (MAT) is a web platform designed to help patients, caregivers and health care providers learn more about some of the resources available to assist in affording their medicines.

www.MAT.org

Recent Life Sciences Announcements



February 2021
RTP (Wake County)
275 new jobs
\$5 M investment



December 2020
Durham (Durham County)
200 new jobs
\$150 M investment



January 2021
Durham (Durham County)
202 new jobs
\$83 M investment



November 2020
Durham (Durham County)
650 new jobs
\$590 M investment



December 2020
Durham (Durham County)
201 new jobs
\$75 M investment



November 2020
Rocky Mount (Edgecombe Co.)
68 new jobs
\$4.5 M investment



December 2020
Greenville (Pitt County)
500 new jobs
\$500 M investment



October 2020
Durham (Durham County)
878 new jobs
\$61.5 M investment



December 2020
Maxton (Scotland County)
10 new jobs
\$1.9 M investment



October 2020
Durham (Durham County)
100 new jobs

Recent Life Sciences Announcements (cont.)



August 2020
RTP (Durham County)
201 new jobs
\$83 M investment



January 2020
RTP (Durham County)
460 new jobs
\$470 M investment



June 2020
Clayton (Johnston County)
300 new jobs
\$351.6 M investment



November 2019
Durham (Durham County)
749 new jobs
\$73 M investment



June 2020
Durham (Durham County)
398 new jobs
\$100 M investment



August 2019
Sanford (Lee County)
300 new jobs
\$500 M investment



February 2020
Sanford (Lee County)
209 new jobs
\$109 M investment



July 2019
Durham (Durham County)
400+ new jobs
\$650 M investment

Additional NC Life Science companies

baebies

 bluebirdbio

bio  cryst

 Biogen

 COOK
MEDICAL

 FUJIFILM
DiOSynth
biotechnologies

 G1
THERAPEUTICS

  glenmark
A new way for a new world

 gsk
GlaxoSmithKline

 IQVIA
BIOTECH

 KRIYA
THERAPEUTICS

 mayne pharma

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PLUS: Deal of the Year ♦ West Virginia Governor's Report

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Questions and Wrap Up



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Meeting adjourned

