

Navigating the Pharmaceutical Supply Chain: Ensuring Access to Prescription Medicines

Moderator: Missouri Representative Gretchen Bangert, Midwestern Regional Director, Women In Government Board of Directors

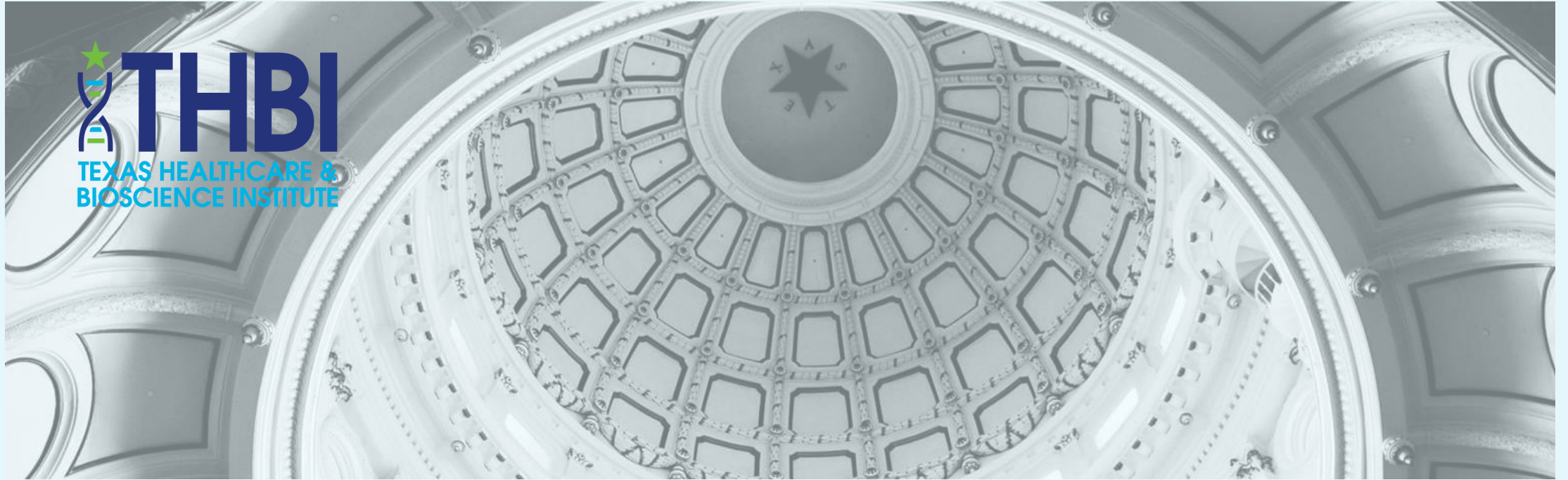
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#AccessToHealthCare



Women In Government: Navigating the Pharmaceutical Supply Chain: Ensuring Access to Prescription Medicines

Presented by Danielle Bush, Director of Policy

We are in a New Era of Medicine Where Breakthrough Science is Transforming Patient Care

60 new medicines were approved by the FDA in 2021.



Cancer Treatments

Cancer mortality rates continue to decline amid 'major progress' in lung cancer early detection and treatment



Game Changer

Newly approved drug being called 'game changer' for people who suffer from hemophilia



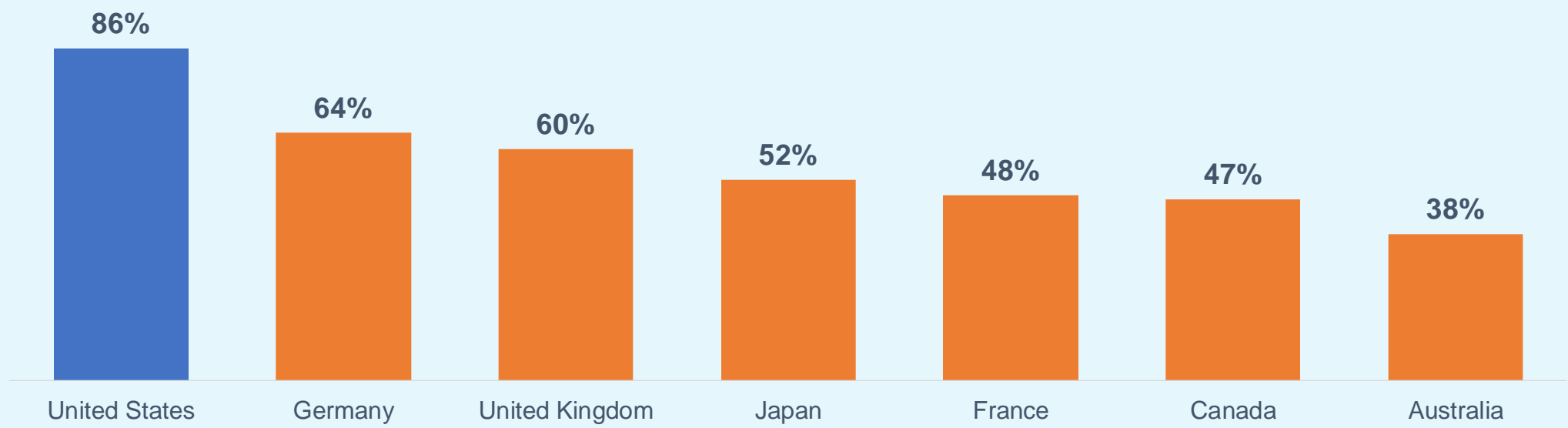
Coronavirus Treatments

FDA authorizes new Covid antibody drug to fight omicron variant

More Medicines are Available to U.S. Patients as Compared with Other Countries that Set Prices Artificially Low

The 5-year survival rate for all cancers is 42% higher for men and 15% higher for women in the U.S. than in Europe.

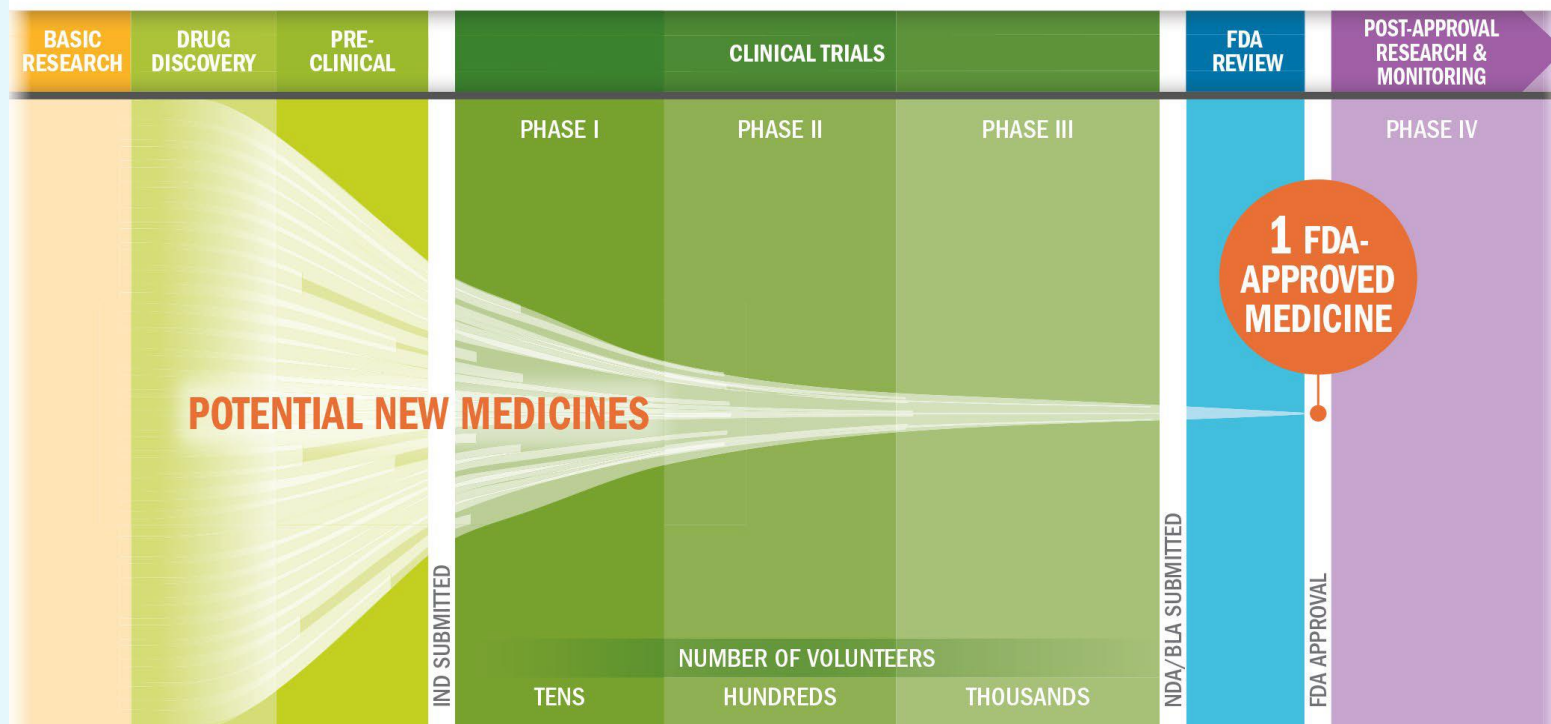
Number of New Medicines Available by Country, 2011-2020



Source: PhRMA analysis of IQVIA Analytics Link and U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA) and Japan's Pharmaceuticals and Medical Devices Agency (PMDA) data. April 2021.
Note: New active substances approved by FDA, EMA and/or PMDA and first launched in any country between January 1, 2011, and December 31, 2020. Many launched medicines are subject to additional government coverage restrictions.

THE BIOPHARMACEUTICAL RESEARCH AND DEVELOPMENT PROCESS

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

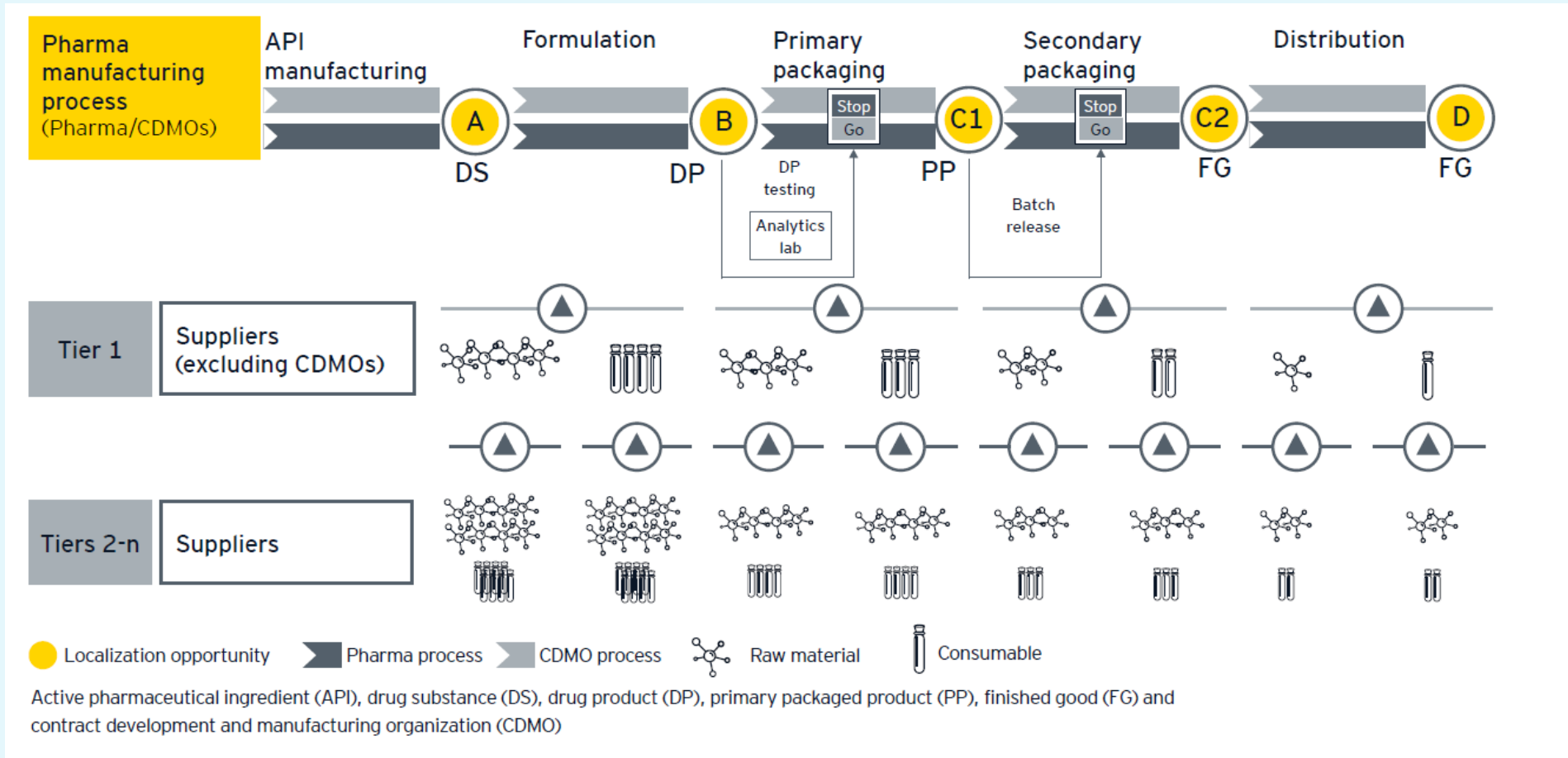


Key: IND: Investigational New Drug Application, NDA: New Drug Application, BLA: Biologics License Application

* 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.

Source: PhRMA adaptation based on Tufts Center for the Study of Drug Development (CSDD) Briefing: "Cost of Developing a New Drug," Nov. 2014. Tufts CSDD & School of Medicine and US FDA Infographic, "Drug Approval Process," <http://www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/UCM284393.pdf> (accessed Jan. 20, 2015).

Opportunities for Localization in the Supply Chain



Manufacturing the Innovations

While the research and development (R&D) of a medicine is under way, a parallel process is undertaken to develop the manufacturing process and build manufacturing capacity - an often-overlooked part of a medicine's lifecycle.

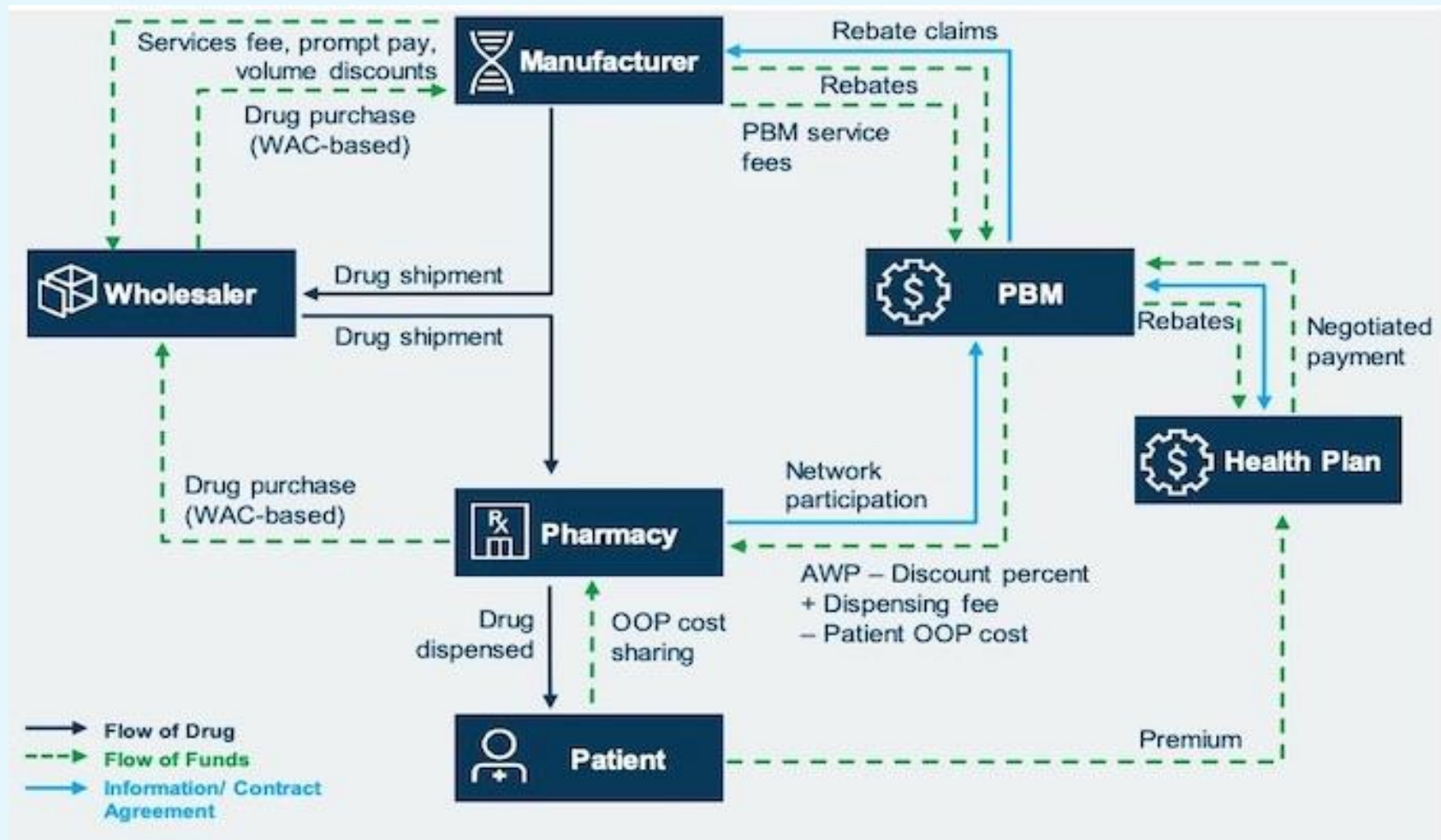
As the R&D process progresses and researchers get closer to a potential successful treatment, companies must make the transition from manufacturing small exploratory batches of experimental medicines used in clinical trials to safely and efficiently manufacturing a medicine in mass quantities for the public, and they must develop the distribution system to get the medicine to patients.

- Establishing a robust manufacturing supply chain;
- Building the capacity to manufacture sufficient quantities of a medicine for the patients that need it;
- Developing and implementing supply chain management plans focused on quality controls related to every aspect of manufacturing and efforts to ensure continuity in manufacturing; and
- Obtaining the appropriate regulatory approvals for any new facilities needed to manufacture the medicine.

Protecting Public Health: Supply Chain Policy Interventions

- In the US, recent policy trends have revealed a bipartisan focus on rebuilding domestic pharma manufacturing capabilities to address concerns over national security and public health and safety. Both the Trump and Biden administrations targeted accelerated vaccine and antiviral drug production and increased stockpiles (via, e.g., Operation Warp Speed and the Defense Production Act), including the use of rated orders to prioritize supply for vaccine development and manufacturing.
- A year-long review of the US' public health supply chains, published in February 2022, reaffirms the Biden administration's ongoing efforts to encourage domestic production and innovation, develop redundancies and ensure that diversification within drug supply chains will continue.
- We can therefore expect to see policymakers explore a broader range of interventions in the industry's operations including:
 - R&D credits and incentives are proactive measures deliberately designed to encourage the local development and manufacturing of pharma products.
 - Place restrictive conditions on pharma supply chains, either by constraining local competition (through limiting market access and investment or imposing export quotas) or by imposing certain conditions on local companies (via procurement mandates or government-incentivized supply chain diversification).

Understanding the Flow from Drug Development to Patient



Biopharmaceutical Trade Supports the Texas Economy and a Large, Diverse Workforce



Economic Output

\$76.5B

Total Value of Goods and Services Supported by the Biopharmaceutical Sector



Biopharmaceutical Manufacturing Plants

68

Facilities Involved in the Manufacturing of Medicines



Tax Revenue Generated

\$3.4B

Total State and Federal Taxes Paid



Venture Capital Investment

\$3.6B

2000-2020 Total VC Investment

181

Startup Companies



Average Worker Compensation

\$133,090

Annually Per Employee in Direct Jobs in the Biopharmaceutical Sector

vs.

\$65,841

Annually Per Employee Across All Texas Jobs

The Role of Wholesale Distributors

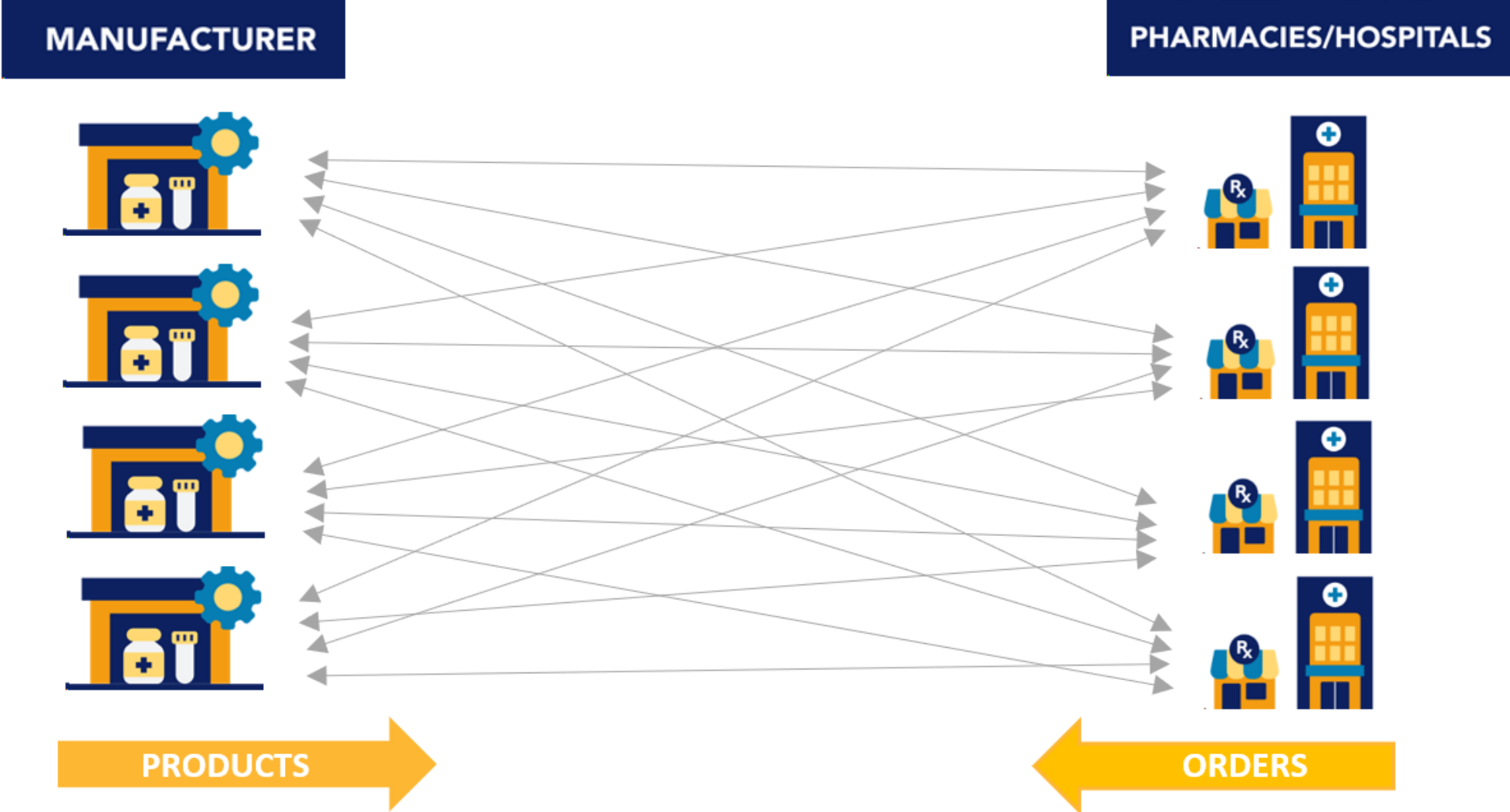
Leah Lindahl

Vice President, State Government Affairs

Healthcare Distribution Alliance

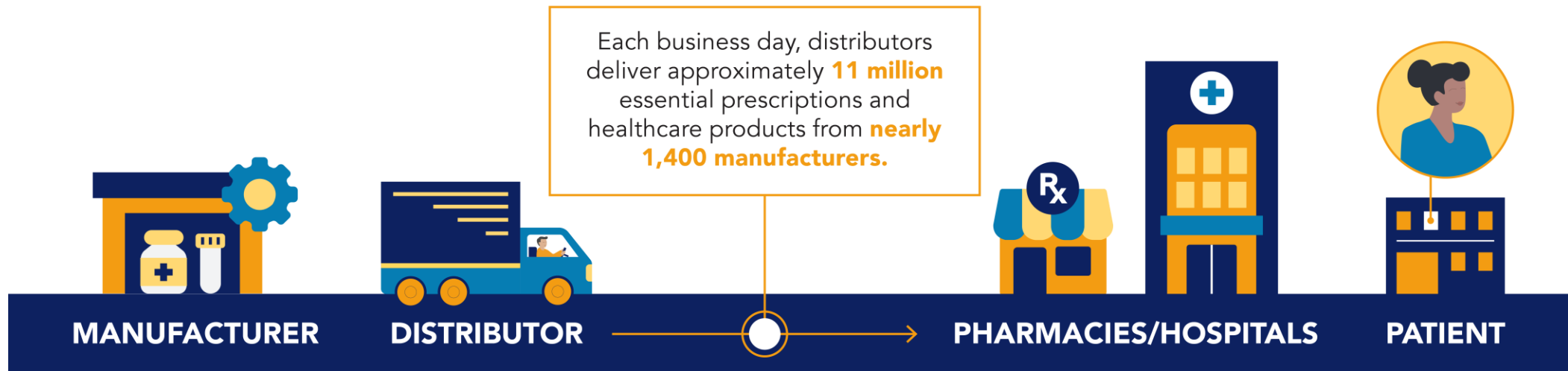


Without Wholesale Distributors



Role of Distributors

Pharmaceutical Distributors: The backbone of the U.S. Healthcare ecosystem



Nearly 330,000 pharmacies and healthcare providers place orders for medicines with distributors.

Source: HDA Research Foundation, 93rd Edition HDA Factbook: The Facts, Figures and Trends in Healthcare (2022–2023), 2022.

Wholesale Distributors Support Points of Care

- Distributors supply products to roughly 330,000 pharmacies and other points-of-care across the nation.
- Pharmacies place orders with distributors for the medicines and products they need, and distributors process, pack and deliver the orders safely and reliably — as soon as the next day.
- On a typical business day, each traditional distribution center picked more than 105,000 SKUs and processed about 4,000 customer orders.
- HDA members fulfilled an estimated 94% of all U.S. pharmaceutical sales.
- Distributors provide many services that allow pharmacies and healthcare providers to focus on the health of their patients:
 - Inventory management;
 - Business and technology solutions;
 - Financial services; and,
 - Independent pharmacy support programs.



Delivering Savings and Efficiencies

VALUE-ADDED SERVICES TO ENSURE
THE SAFE AND TIMELY DELIVERY OF



HDA DISTRIBUTORS REPRESENT



\$570 BILLION ANNUALLY

PROVIDE UP TO

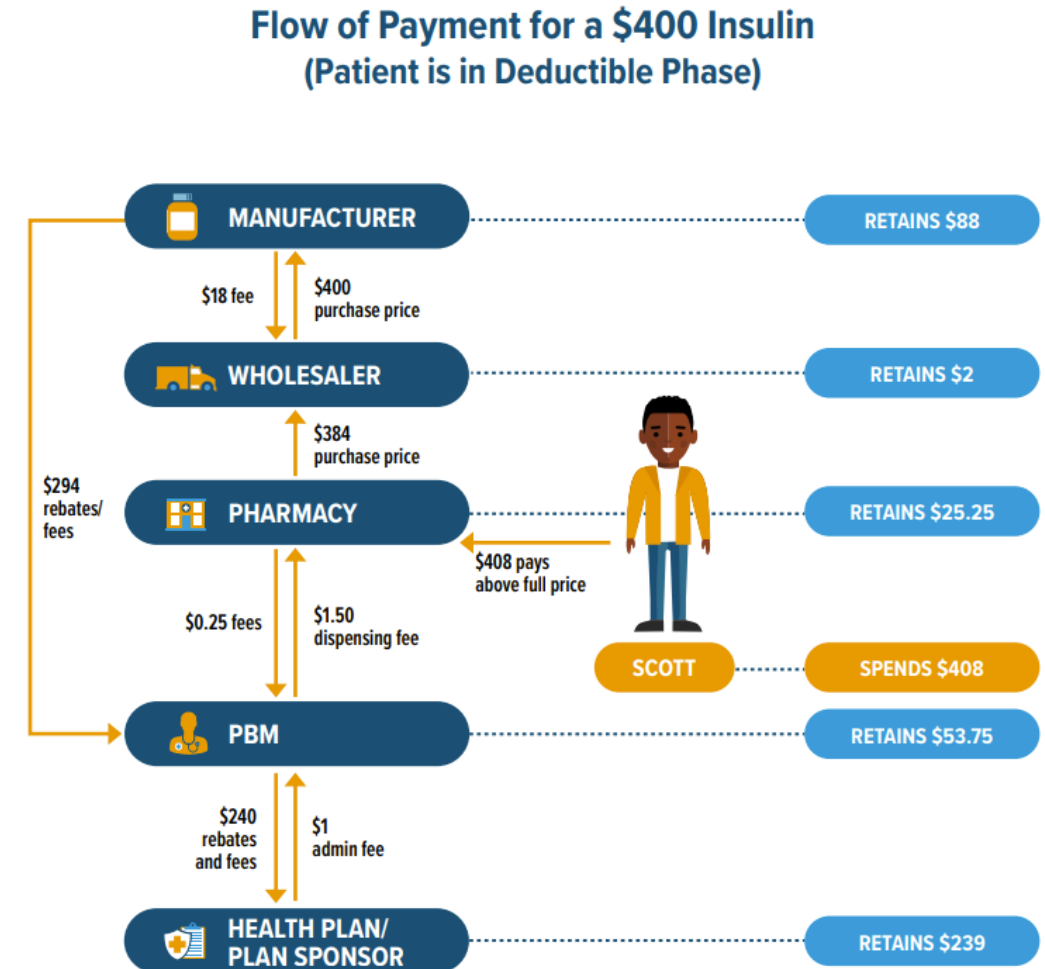
\$63

BILLION IN SAVINGS

**TO THE HEALTHCARE
ECOSYSTEM ANNUALLY**

Wholesale Distributors & Pricing

- Pharmaceutical wholesale distributors primarily utilize a **fee-for-service model**.
- The pharmaceutical distribution model is a high value, high volume but very low margin industry. A recent analysis from Berkeley Research Group (BRG) shows the profit margin for a wholesaler is **less than one percent** of the cost of brand medicines.
- Findings consistent with reports and analyses by the *USC*, *PhRMA*, *Wall Street Journal* and *Kaiser Health News*.



*This graphic is illustrative of a hypothetical product with a WAC of \$400 and an AWP of \$480. It is not intended to represent every financial relationship in the marketplace.

**The amount of payments does not add up to \$400 due to markups and discounts as medicines are distributed.

State Legislative Issues

Supply Chain Stability

- DSCSA Implementation
- Pricing and data collection measures
- Reproductive Health
- Taxes and Fees

Supporting Downstream Customers

- Pharmacy Services Administrative Organizations (PSAO)
- Controlled Substance
- White Bagging

Regulatory

- Licensure
- Scheduling
- Reporting
- Stockpiling

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TEXAS *Pharmacy Association*
Together Pharmacy Advances

The Pharmaceutical Supply Chain: Ensuring Access to Prescription Medicines

Debbie Garza, R.Ph.

CEO, Texas Pharmacy Association

November 2, 2023



Texas Pharmacy Overview

- Texas Pharmacies (>8,000)
 - >3,000 Chain
 - >1,600 Independent
- Texas Pharmacists
 - 36,000 Licensed
- Pharmacists are the most accessible providers
 - 91% of Texans live within 5 miles of a pharmacy
- Pharmacists are highly educated
 - Doctor of Pharmacy (Pharm.D.) degree can take 6 to 8 years to obtain
 - Many pharmacists complete a one- or two-year postgraduate residency program





Evolving Role of Pharmacists



**Healthcare
Provider**

Trusted Professional



Medication Expert



Texas Pharmacy Policy Issues

PBM Reform

Address egregious acts by PBMs to ensure patient choice, prohibit unfair business practices, and eliminate PBM self-dealing

Vaccination Expanded Authority

Make permanent PREP Act authority for RPh to order and administer vaccines to 3 years and older; techs able to administer

Test & Treat

Allow pharmacist to initiate medication for positive CLIA-waived test for COVID-19, flu, and strep throat





Vertical Integration

Vertical Business Relationships Among Insurers, PBMs, Specialty Pharmacies, and Providers, 2023



Big 3 PBMs control approx. 80% of prescription drug claims!

24% PBM market share
Fortune 15

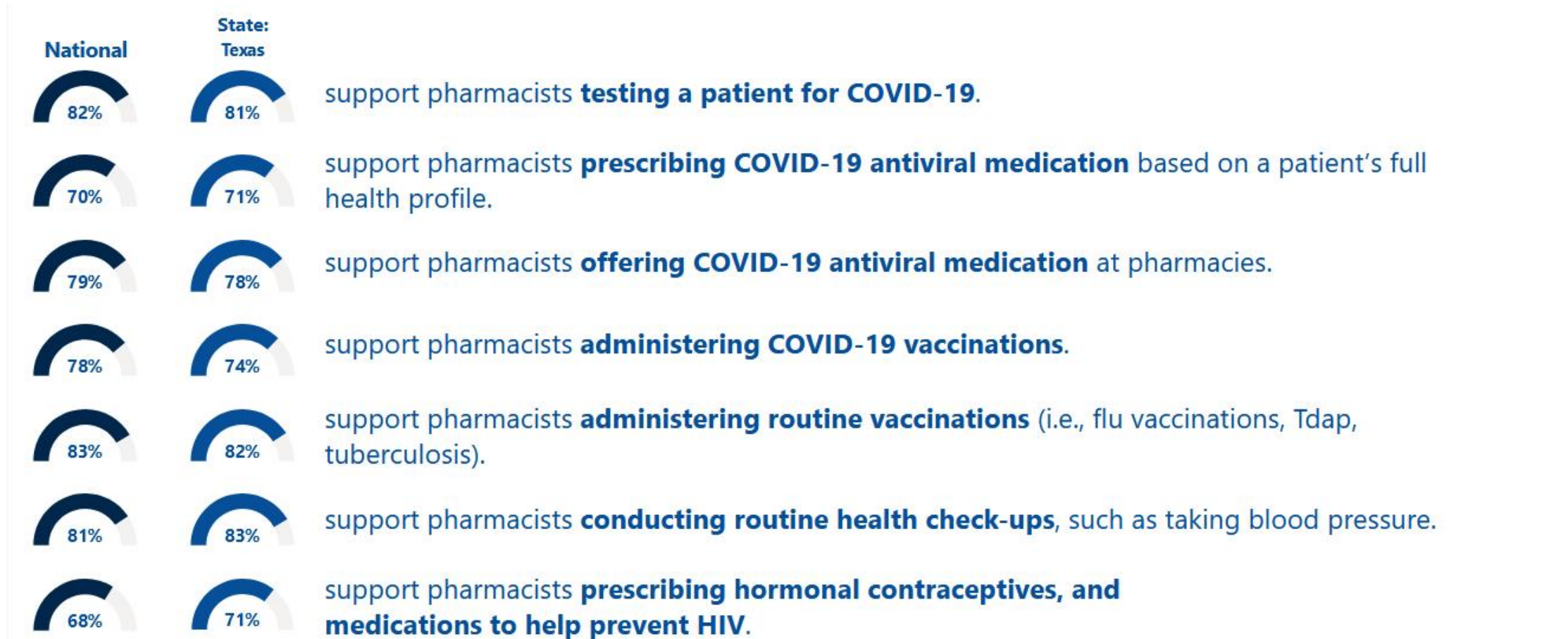
33% PBM market share
Fortune 6

22% PBM market share
Fortune 5



Texas Voters Agree

Patients Support Pharmacists' Roles Beyond Dispensing





Texas Voters Agree

Patients Support Pharmacists' Roles Beyond Dispensing

