

# Principles to Promote Access to Essential Medicines and Reduce Out-of-Pocket Costs for Patients

(Updated 10/1/21)

**The U.S. healthcare supply chain is a complex system, with multiple stakeholders — but it also is one of the most sophisticated, efficient and secure distribution systems in the world. The distributor members of the [Healthcare Distribution Alliance \(HDA\)](#) provide approximately **\$63 billion in cost savings** to the U.S. healthcare economy each year. But our primary mission is to provide safe and secure access to the highest quality medicines to the nation’s healthcare providers and the patients in their care.**

## Background

Pharmaceutical wholesale distributors are responsible for the storage and delivery of 95 percent of medicines in the U.S. Moving medicines safely and securely from manufacturers to pharmacies and hospitals across the country requires significant logistics expertise and distribution capabilities. While the vast majority of pharmaceutical products flow through wholesale distributors, they also are the lowest-cost and most efficient link in the supply chain, in most cases providing next-day service to healthcare providers. A study by the [University of Southern California Schaeffer Center for Health Policy & Economics](#) shows that wholesalers are able to operate on the smallest margins of any other entity in the healthcare supply chain.

Every day, pharmacies, hospitals and other healthcare providers place orders with distributors for the medicines, supplies and equipment they need to serve their patients. In turn, distributors ensure that their distribution centers are stocked with every potential medicine, supply and piece of equipment their provider customers may need. Meanwhile, cost-effective delivery provides savings to the healthcare system by ensuring patients and providers can access the medicines they need when they need them.

## Central Role in Supply Chain

In the context of the drug pricing debate, it is important to note the clear distinction between the role that wholesale distributors play in the physical handling and distribution of essential medicines in the supply chain versus the role that other entities play in the payment chain. Distributors play a central role in ensuring the safe and efficient movement of vaccines, therapeutics and supplies from manufacturers to frontline providers and pharmacies who are treating patients.

In contrast, payment chain entities, such as health plans and pharmacy benefit managers (PBMs), often never touch or handle products — or see patients, for that matter. Their role is to serve as financial gatekeepers and determine which medicines a patient can access and the costs associated with that particular medicine.

These distinct and wholly separate roles are frequently conflated by policymakers and require clarity as the debate about access and affordability evolves.

## Services to Provider Customers

Beyond managing the safe and secure movement of essential medicines, pharmaceutical distributors provide a wide array of services that enable the pharmaceutical supply chain to function efficiently and safely, delivering significant value to manufacturers, pharmacists, healthcare providers and ultimately to patients. These services include providing information technology and data systems that help manage inventory and verify provider orders. Distributors also have strong capabilities to manage operational risks, such as identifying suspect and illegitimate products and assisting with recalls.

## Supporting Access and Affordability

Given our industry's mission to ensuring safe and affordable healthcare for all Americans, HDA and our members support affordability solutions that will reduce costs while building on the efficiency and reliability the American pharmaceutical supply chain currently delivers. HDA supports improving access to and affordability of innovative new therapies as well as lower-cost, high-quality generic and biosimilar medicines for patients through a variety of ways:

### **Promote accelerated approvals for lifesaving medications:**

HDA supports prompt Food and Drug Administration (FDA) review of innovative, lifesaving medicines. This includes novel treatments to address COVID-19, breakthrough therapies to treat rare disorders and other intractable diseases like cancer. This also includes expedited review and approval of generic medicines once innovator patent exclusivity has lapsed.

### **Increase patient access to lower-cost biosimilar products:**

Prompt review and approval of biosimilars products will help alleviate costs on some of the most expensive medicines available today. While it is important to encourage continued innovation and reward companies that invest in research and development, there should also be a realization that the cost of these medicines can present significant obstacles to access, particularly for the uninsured or fixed-income individuals who may have insurance but cannot afford significant co-pays.

If biosimilars are approved as interchangeable, HDA supports efforts to incentivize the prescribing of these medicines. These incentives could include preferred formulary placement for biosimilars and/or increasing reimbursement rates for physicians who prescribe and administer biosimilars, and/or reduced cost-sharing for patients receiving approved biosimilars.

### **Support policies that prevent pay-for-delay settlements that prolong the entry of lower-cost medicines, including generic drugs and biosimilars:**

The Hatch-Waxman Act of 1984 put in place a carefully balanced regulatory framework designed to facilitate the introduction of lower-cost generic drugs while preserving incentives for innovation.

However, efforts over time to prolong exclusivity or delay entry of competing products have prevented lower cost medicines from entering the pharmaceutical marketplace. According to the [Federal Trade Commission \(FTC\)](#), these anticompetitive deals cost consumers and taxpayers \$3.5 billion in higher drug costs every year. Since 2001, the FTC has filed a number of lawsuits to stop these deals, and it supports legislation to end such "pay-for-delay" settlements.

Once fair and equitable exclusivity periods lapse for an innovative drug product and a generic or biosimilar product is available, the FDA should be able to review and approve lower-cost alternatives. Tactics that prevent the introduction of lower-cost medicines (once exclusivity periods have lapsed) should be constrained.

### **Support policies that reduce out-of-pocket costs and lower maximum caps for patients, particularly older Americans:**

Americans who face the greatest burden from healthcare cost pressures are usually the most vulnerable: seniors and those with very serious or chronic conditions and often those with the least generous insurance or no insurance at all.

Compounding these inequities are the disparities patients face between different types of treatment and access to care. These challenges can lead to some patients foregoing their medicines entirely which often leads to even more costly medical interventions. To fulfill the goal of stable, secure and affordable healthcare for all — including the most medically vulnerable — it is important to consider patient cost caps across the entire commercial healthcare and insurance market.

## Support giving pharmacists provider status to help increase access to healthcare and lower costs:

Pharmacists are highly skilled medical professionals, who, in addition to being highly trusted by the patients they serve, are readily accessible in most American communities and have been frontline heroes in our nation's fight against COVID-19. However, unlike their physician counterparts, pharmacists' legal capacity to assess, prescribe and administer medicines is limited and varies from state to state.

During a time in which every provider is a vital resource, more patients receiving basic medical care and services at the pharmacy frees up physician offices and hospitals for more urgent care.

Pharmacists already are an integral part of the U.S. healthcare system, providing invaluable guidance to their patients and advocating on their behalf, improving patient outcomes, improving efficiency and reducing the cost of care. In addition to prescribing basic medicines, pharmacists also could be tapped to conduct and order diagnostic tests, counsel patients and initiate treatment where appropriate.

Granting pharmacists provider status will immediately help relieve a healthcare system that is currently strained for resources.

## Conclusion

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Healthcare distributors play a vital role in the lives of Americans by helping to ensure that essential medicines needed to maintain or restore health are readily accessible to healthcare providers. Hospitals, retail pharmacies, physician offices and other providers rely on daily deliveries of products from a healthcare distributor to keep their shelves stocked with lifesaving or life-improving medicines while carefully managing inventory expenses.

HDA distributor members are committed to working with public officials and healthcare leaders to improve access to and reduce costs. The policies referenced above would help improve access to lifesaving medicines while reducing expenditures and lowering patient out-of-pocket costs.

## About the Healthcare Distribution Alliance

The Healthcare Distribution Alliance (HDA) represents primary pharmaceutical distributors — the vital link between the nation's pharmaceutical manufacturers and pharmacies, hospitals, long-term care facilities, clinics and others nationwide. Since 1876, HDA has helped members navigate regulations and innovations to get the right medicines to the right patients at the right time, safely and efficiently. The HDA Research Foundation, HDA's nonprofit charitable foundation, serves the healthcare industry by providing research and education focused on priority healthcare supply chain issues.