

Generic Drugs: Improving Access & Quality

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2020 Generic Drug Forum
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@QualityKop

Pharmaceutical Quality



A quality product of any kind consistently meets the expectations of the user.



Pharmaceutical Quality



A quality product of any kind consistently meets the expectations of the user.



Drugs are no different.

A close-up photograph showing a hand holding an orange pill bottle, pouring three white, oval-shaped pills into the palm of another hand. The background is blurred, focusing attention on the action of taking medication.

**Patients expect safe and effective
medicine with every dose they take**

A close-up photograph of a person's hands. The left hand is holding an orange plastic pill bottle, tilted to pour three white, oval-shaped pills into the palm of the right hand. The background is blurred, focusing attention on the action of dispensing the medication.

Pharmaceutical quality is
assuring *every* dose is safe and
effective, free of contamination
and defects



It is what gives patients confidence
in their *next* dose of medicine

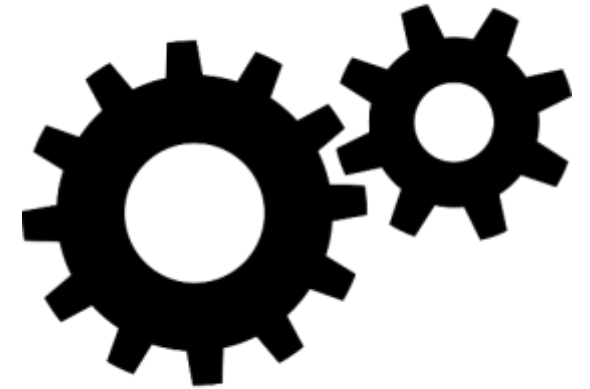
Outline



- **How the FDA Regulates Generic Drug Quality**
- **What Patients Think About Generic Drug Quality**
- **What We Can Do About Drug Shortages**
- **Join Us in a Commitment to Quality**

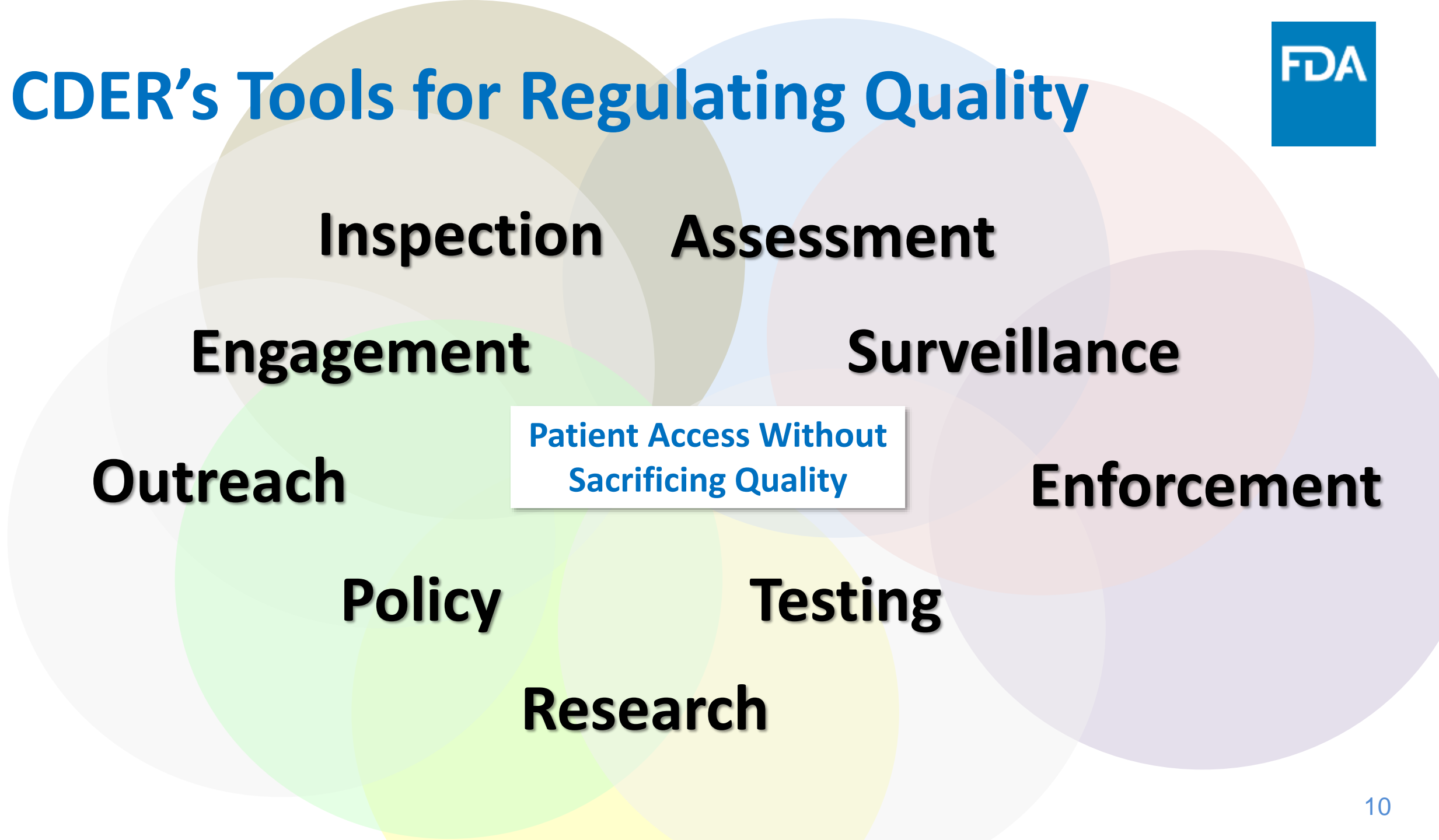
Learning Objectives

- Understand FDA's tools to regulate drug quality
- Recognize the causes of and potential solutions to avoid drug shortages



How Does the FDA Regulate Generic Drug Quality?

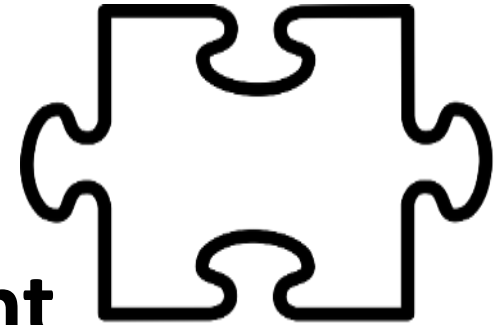
CDER's Tools for Regulating Quality

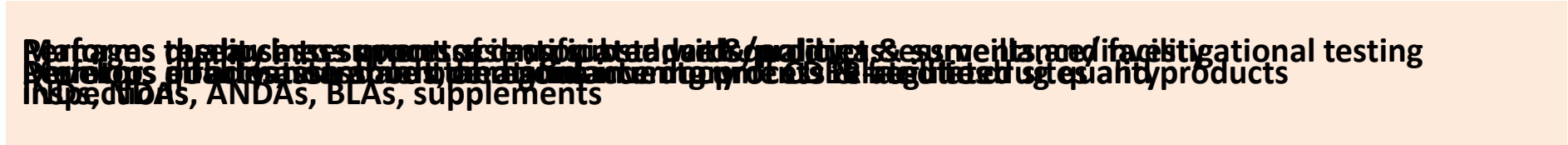


Office of Pharmaceutical Quality (OPQ) Reorg



- **Align to CDER's Office of New Drugs as their structure changes as part of New Drugs Regulatory Program Modernization**
- **Better align within OPQ: managerial oversight and work processes**
 - Additional divisions and branches reduce the staff to supervisor ratios
 - Division names, branch names, and functional statements updated to better describe the work performed





The Pharmaceutical Quality Lifecycle



With a staff of **~1,300** OPQ's quality assessments average in a given year:

- Around **20** biologics
- Around **200** new drugs
- Around **3,000** investigational new drugs
- Around **4,000** generics
- Around **8,000** supplements



One Quality Voice for Patients



We Are Patients, Too.

What Do Patients Think About Generic Drug Quality?

MAY 4 – JUNE 7, 2018



Consumer Knowledge of Drug Quality

FDABAA-16-00122

HHSF223201710128C

3,037 WebMD site visitors

SEPT 25 – OCT 9, 2018



Physician Knowledge of Drug Quality

FDABAA-16-00122

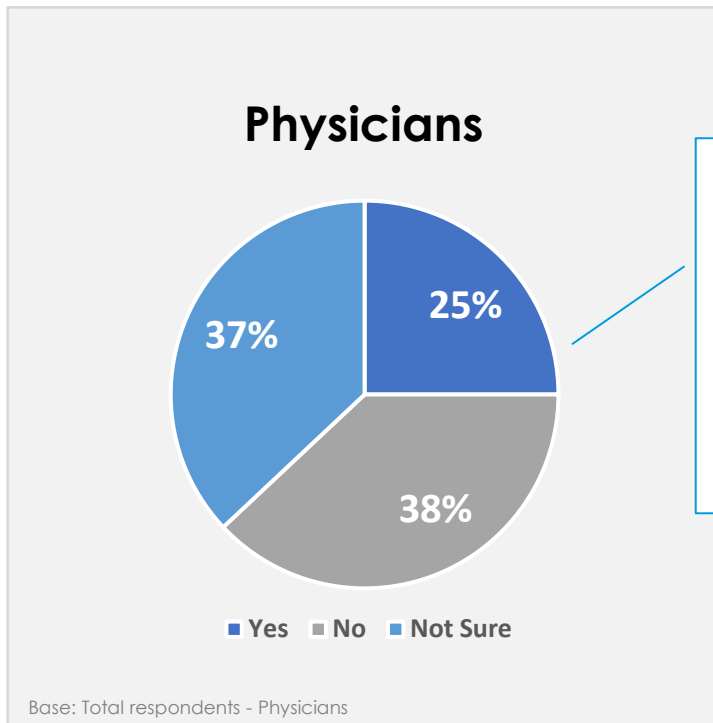
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650 Physicians

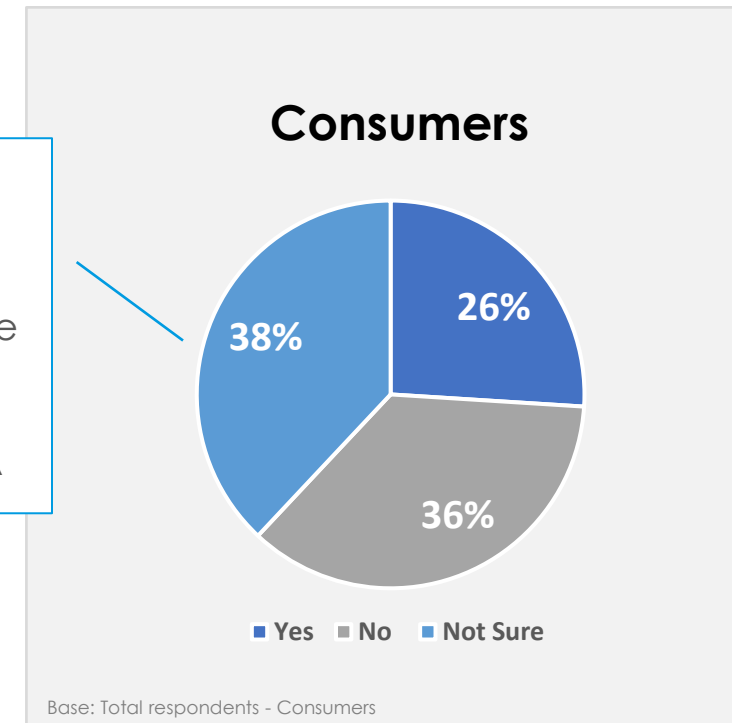
Perceptions of Drug Manufacturing



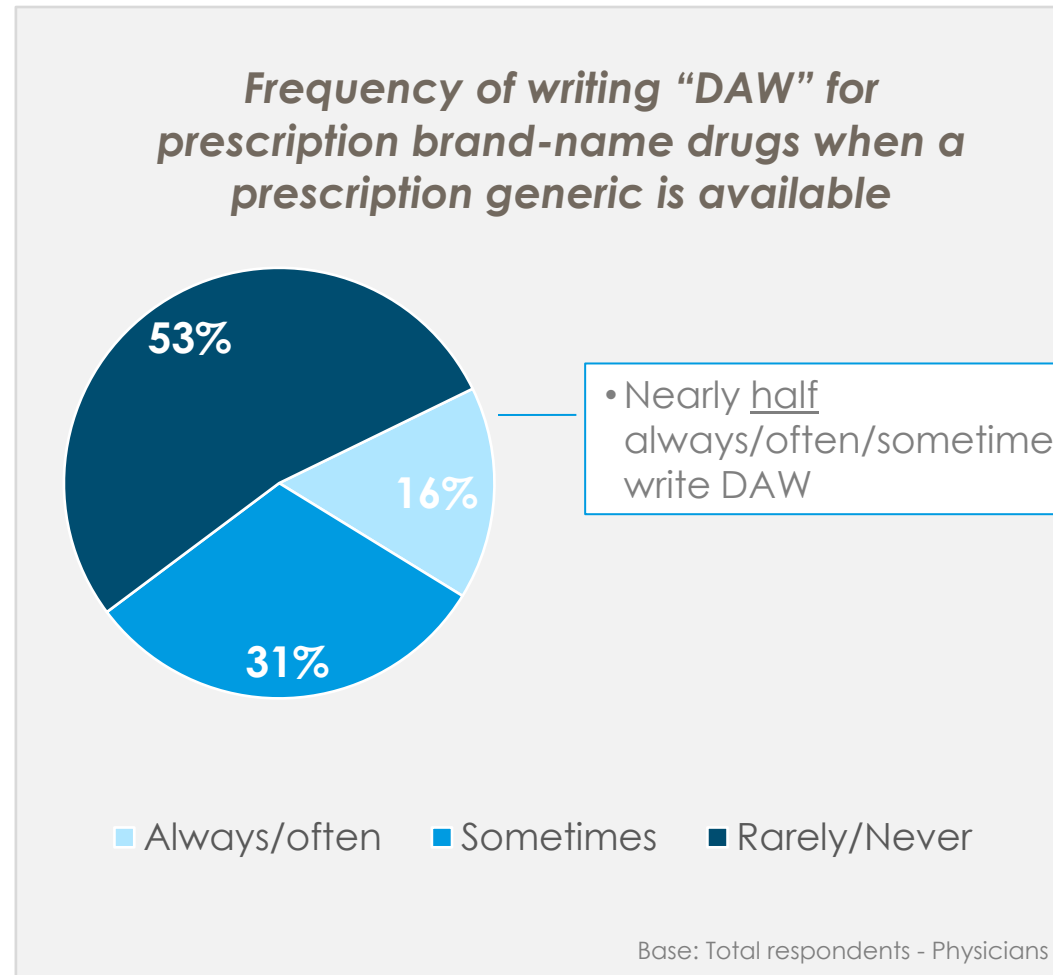
Do you believe drugs manufactured outside the U.S. and sold in the U.S. adhere to strict manufacturing standards and regulations required by the FDA?



- Nearly three quarters of consumers AND physicians **do not believe** or **are not sure** that drugs manufactured outside the U.S. adhere to strict manufacturing standards and regulations required by the FDA

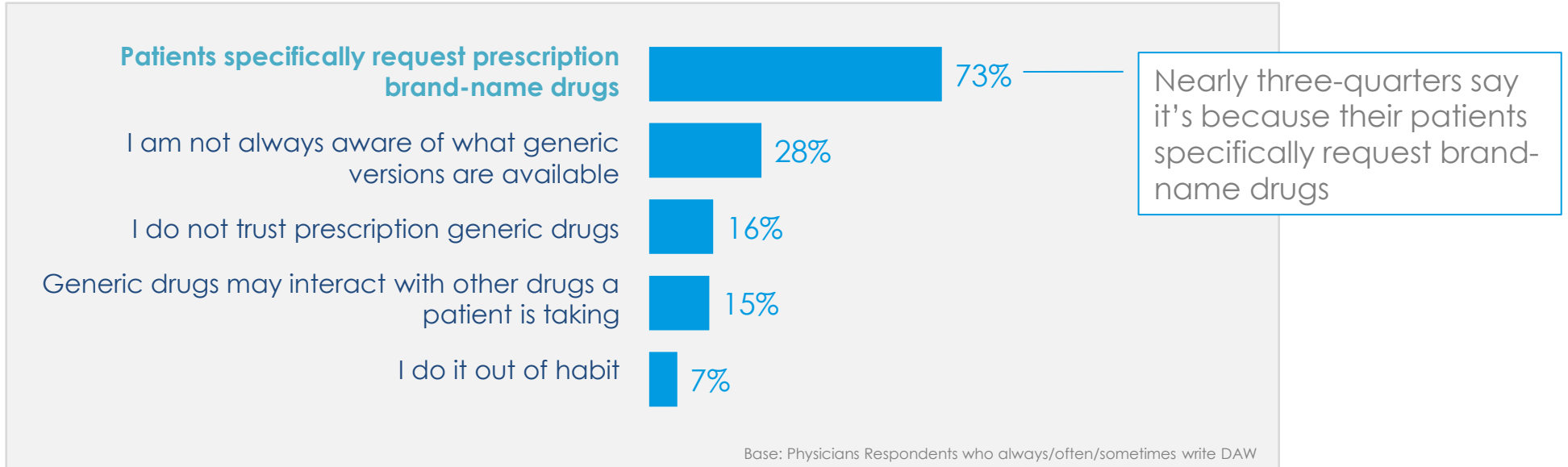


Frequency of Dispense as Written



Reasons for Dispense as Written

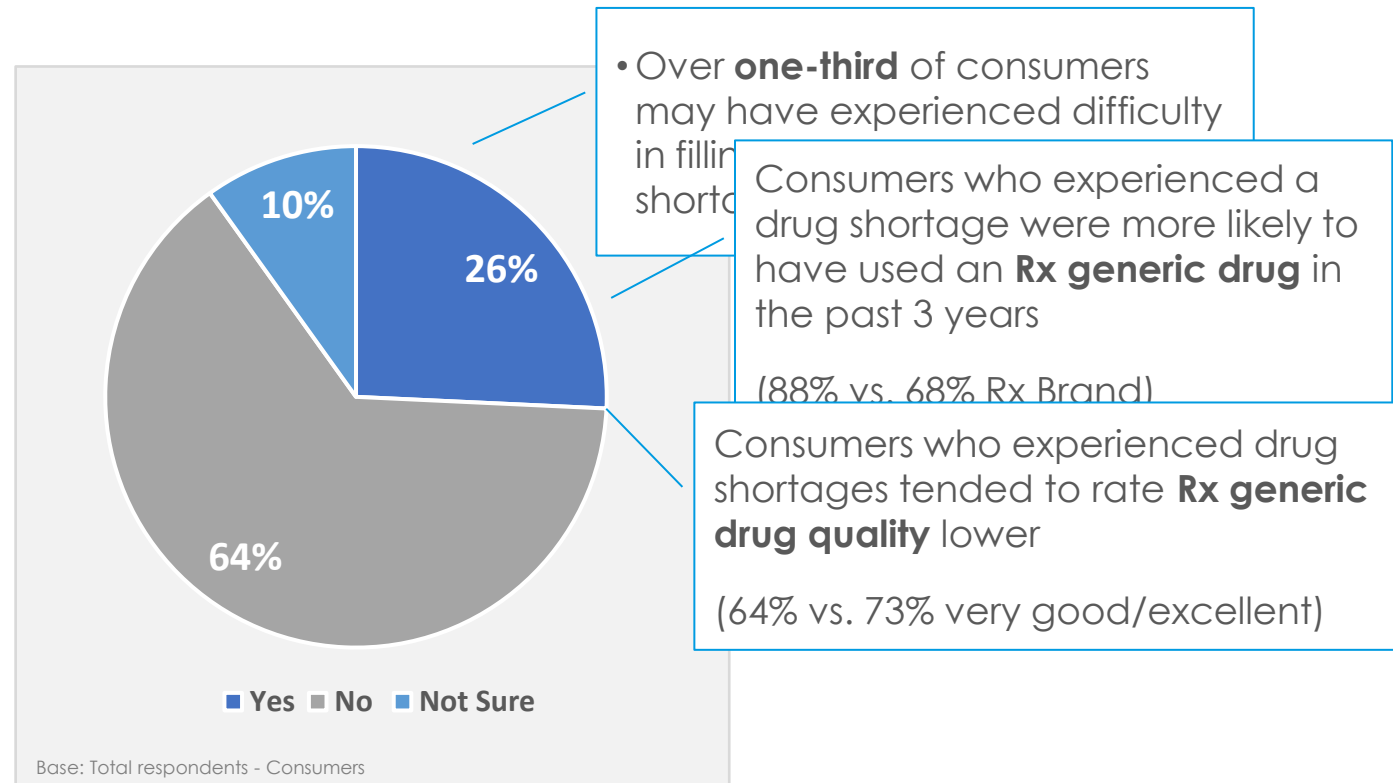
Primary reasons for writing “DAW”



Drug Shortages

Consumers:

Have you experienced any difficulty in filling your prescription(s) due to drug shortage?



What Can We Do About Shortages?



2019

**To Help Reduce Drug Shortages, We Need
Manufacturers to Sell Quality – Not Just
Medicine**

By: Janet Woodcock, M.D., Director, Center for Drug Evaluation and Research

You might not always shop based solely on the lowest price. For instance, if you highly value your time, you may choose a car from a manufacturer with a great reputation for reliability, even though similar cars cost a bit less. Choices based on what you value are common in everyday life. But, unfortunately, when it comes to prescription medications, buyers may not have that option. And in the view of the U.S. Food and Drug Administration, this lack of transparency is contributing to ongoing drug shortages, a critical health care issue that reduces treatment options, limits access to medications, and can threaten the well-being of patients in need of important therapies. Let's take a closer look.

All drug manufacturers that sell their medications in the United States must adhere to the FDA's Current Good Manufacturing Practice (CGMP) requirements. Adherence to CGMP requirements is intended to make sure the drug itself is of adequate quality.

But there's another element to quality in manufacturing — the ability to reliably make the product in sufficient quantities and with sufficient speed to ensure that supply consistently meets demand over sustained periods of time. This is especially true in the pharmaceutical industry, where the product is often life-sustaining — and ongoing access is critical.

Purchasers of prescription drugs such as drug distributors, hospitals, and pharmacies can be assured that FDA-approved medicines have been shown to be safe and effective for their labeled uses. Since these purchasers have tight budgets, they may select the lowest-priced product, in



Incentivizing Investment in Quality Management Maturity



Root causes for drug shortages:

- Lack of incentives for manufacturers to produce less profitable drugs
- Market does not recognize and reward manufacturers for “**mature quality systems**”
- Logistical and regulatory challenges make it difficult to recover from a supply disruption



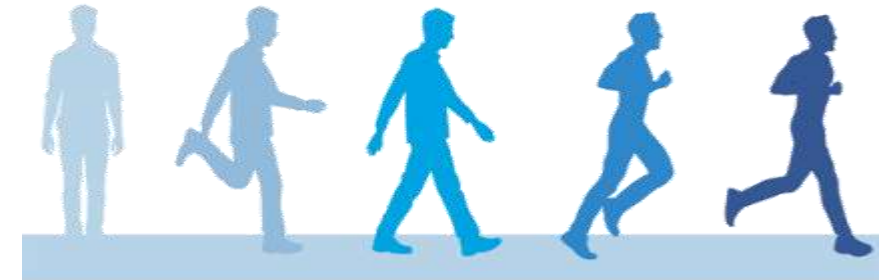
Quality Management Maturity

- **Basic Quality Management Systems**

- *Reactive*: focused on Current Good Manufacturing Practice (CGMP) compliance

- **Strong, mature Quality Management Systems**

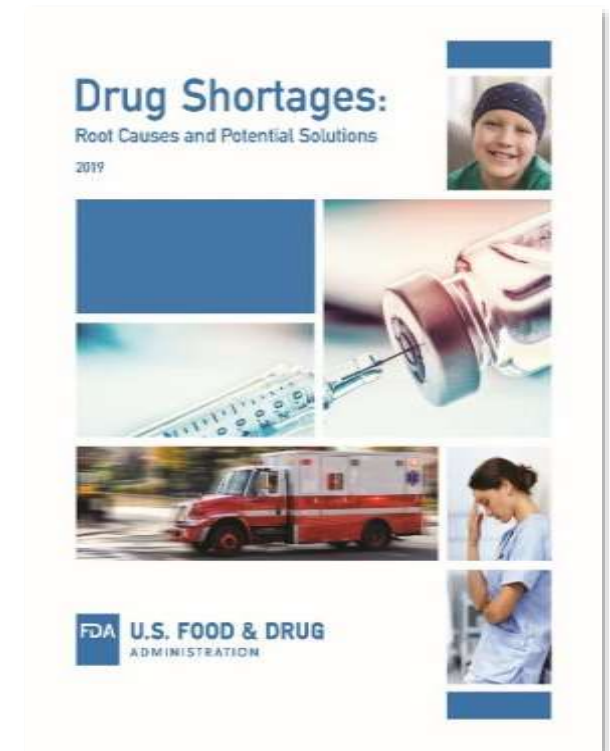
- *Proactive*: focus on performance, especially outcomes that affect the patient



An Enduring Solution: Public Rating System

A rating system to inform purchasers, and patients and consumers, about the quality management maturity of the facilities making their drugs

- Introduce **transparency** into the market
- Provide firms committed to quality management maturity with a **competitive advantage**
- Enable **sustainable prices** as well as grow market share



Join Us in a Commitment to Quality

What This Means...

- **Marketing approved drugs whenever possible**
- **Providing consumers more transparency on quality**
- **Maturing Quality Management Systems**
- **Embracing advanced manufacturing technology**



Challenge Question

- Which of the following is NOT a tool used by the FDA to regulate drug quality?




- APPLICATION ASSESSMENT
- POLICY DEVELOPMENT
- FREESTYLE RAP
- PRODUCT TESTING
- FACILITY INSPECTION

Challenge Question

- Is this statement true or false?

“The majority of generic drugs applications approved by the FDA are not marketed in this country.”



A close-up photograph of a person's hands. One hand is holding an orange plastic pill bottle, tilted to pour several white, oval-shaped pills into the palm of the other hand. The background is blurred, focusing attention on the action of taking medication.

Let's work together so we can all
have confidence in our next *dose* of
medicine

Don't forget we are patients, too



U.S. FOOD & DRUG
ADMINISTRATION