U.S. FOOD & DRUG ADMINISTRATION

An International Commitment to Pharmaceutical Quality

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@QualityKop

Pharmaceutical Quality for Global Stakeholders
July 23, 2020

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.

Patients expect safe and effective medicine with every dose they take

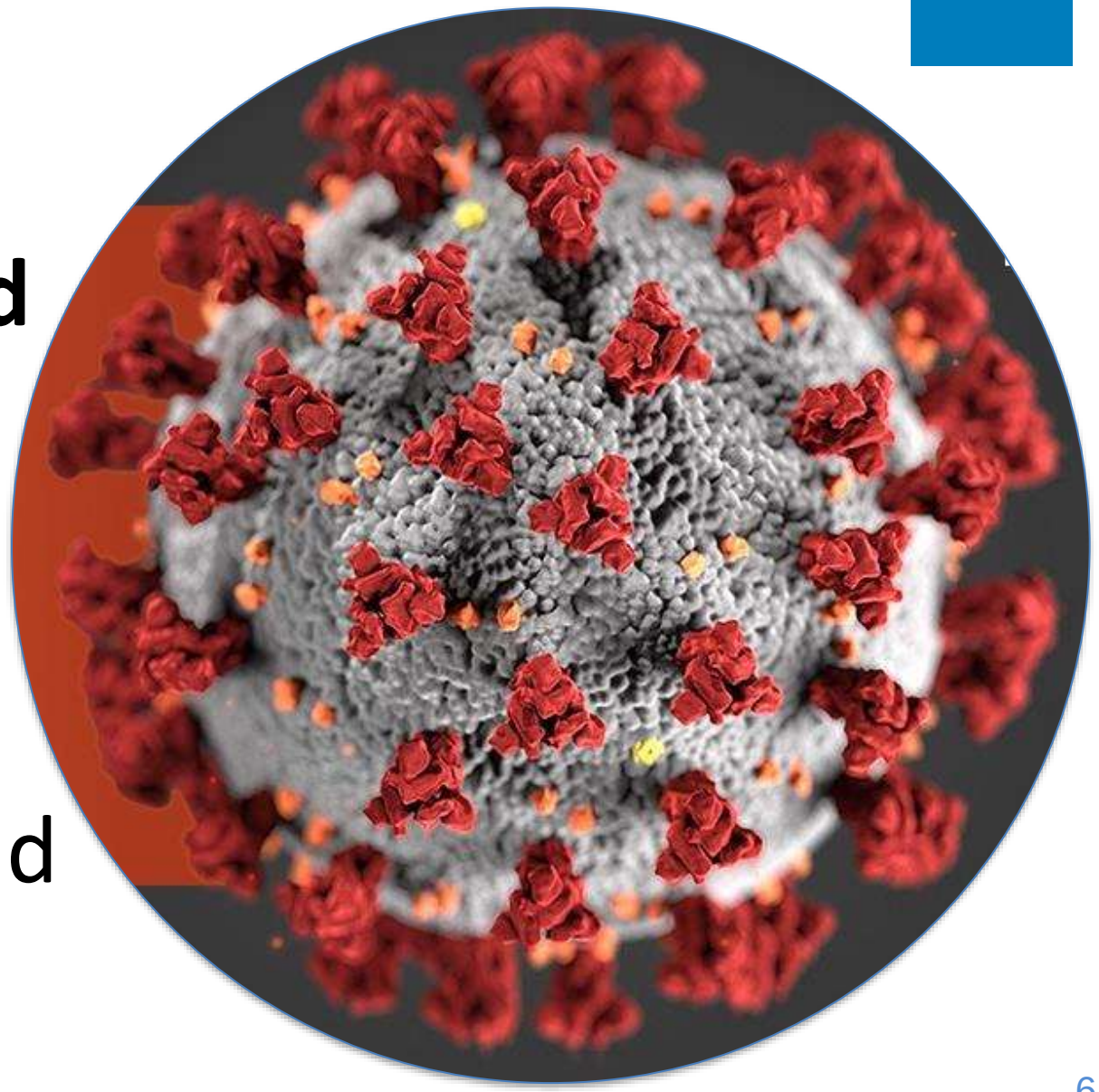
Pharmaceutical quality is

what gives patients confidence in their next dose of medicine

The Era of COVID-19

Long-existing quality issues are now magnified

- Supply chains
- Shortages
- Decision-making based on changing science and risk



A History of Pharmaceutical Quality

1938	1962	2015
Deaths from elixir Sulfanilamide	Children born with severe birth defects from thalidomide	Serious injuries and deaths from global heparin crisis
1938 Food, Drug, and Cosmetic (FD&C) Act	1962 Kefauver-Harris Amendments to the FD&C Act	**FDA establishes Office of Pharmaceutical Quality**
Safety studies required for new drugs	*Need to prove that drugs are safe and effective*	*Integrates functions and elevates FDA's commitment to quality*

2020?

Disruptions are perfect timing for innovations

We need a "better normal"

<u>Different</u> thinking is required

Topics

- The State of Pharmaceutical Quality
- Patient and Physician Perceptions of Pharmaceutical Quality
- Drug Shortages: An Old “New Problem”
- Join Us in a Commitment to Quality

The State of Pharmaceutical Quality

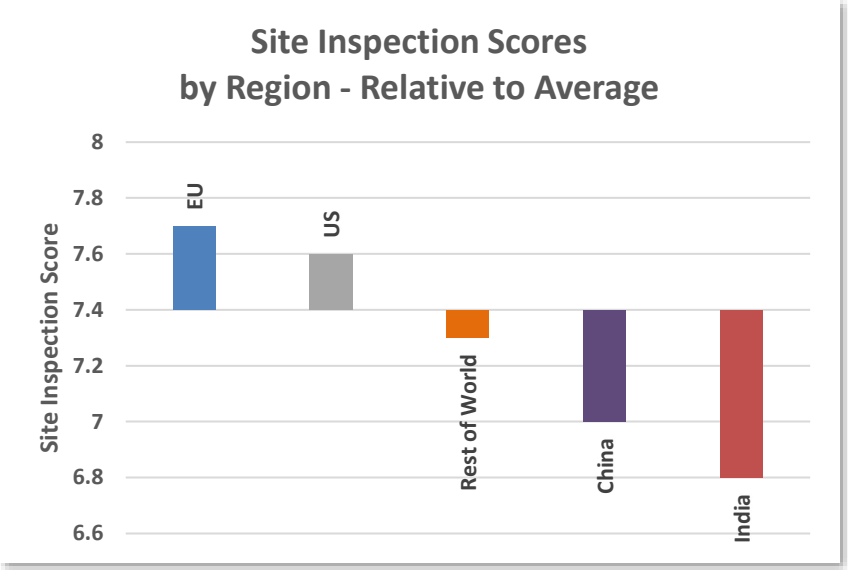
US FDA Center for Drug Evaluation and Research

The State of Pharma Quality: FY19

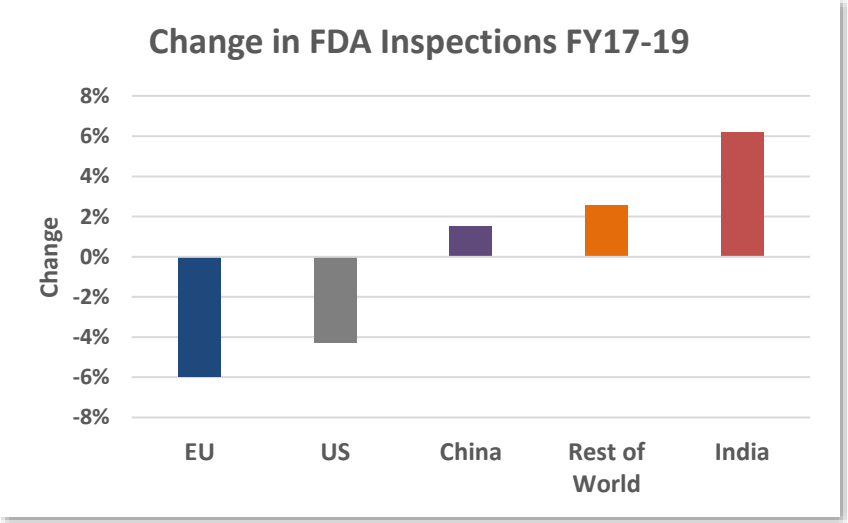
Every year we report select quality indicators and trends to:

- Inform regulatory decision-making and surveillance
- Offer more transparency to patients and consumers
- Engage the pharmaceutical manufacturing industry in a commitment to quality

State of Pharma Quality: Key Findings



Facilities in some regions perform below others



FDA has performed a higher percentage of inspections in these regions (*pre-COVID)

Hear more from Raphael Brykman on The State of Pharmaceutical Quality at 4:05AM EST

Patient and Physician Perceptions of Pharmaceutical Quality

US FDA Center for Drug Evaluation and Research

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

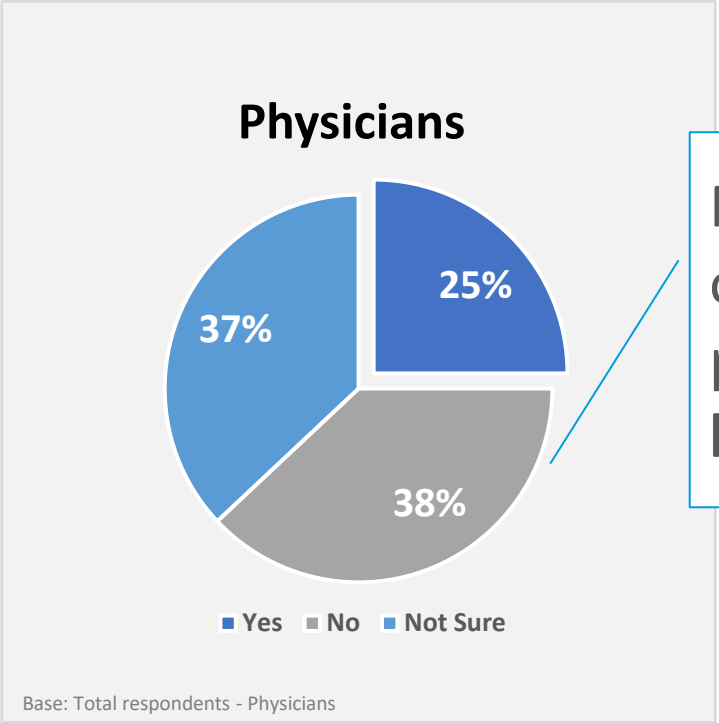
HHSF223201710128C

650 Physicians

WebMD

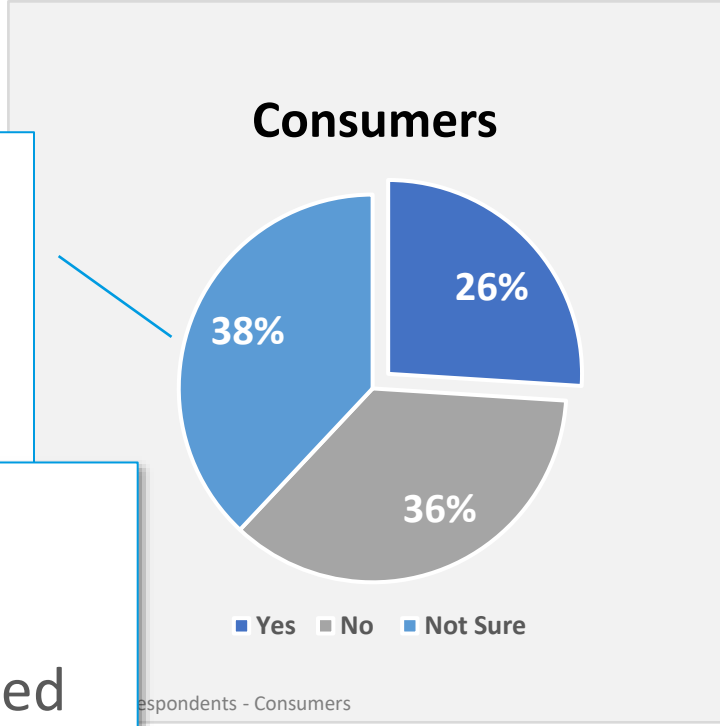
Perceptions of Drug Manufacturing

*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 <u>three quarters</u> of consumers AND physicians **do not believe** or **are not sure**

>70% of API manufacturing facilities are located outside the U.S.

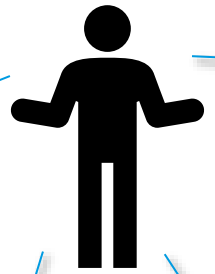


Top Four Reasons Why

Consumers and physicians who say drugs legally sold in the U.S. manufactured outside the U.S. are of lower quality

#1: Not as pure or could be contaminated (>60%)

#2: May be from places that experience health and sanitation problems (>60%)



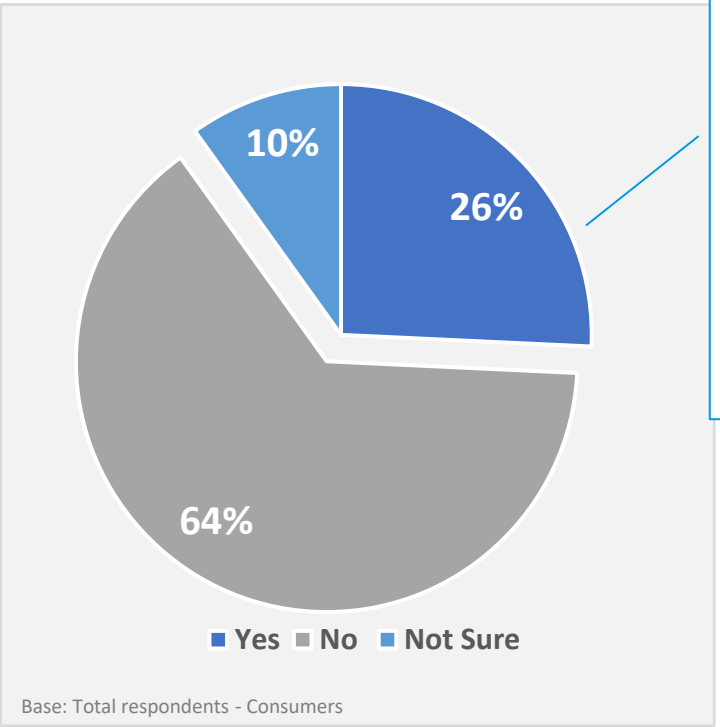
#3: Use inferior active ingredients (>40%)

#4: Have a bad reputation (>25%)

Drug Shortages

Consumers:

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



- Over **one-third** of consumers may have experienced difficulty in filling an Rx due to drug shortage

Drug Shortages: An Old “New Problem”

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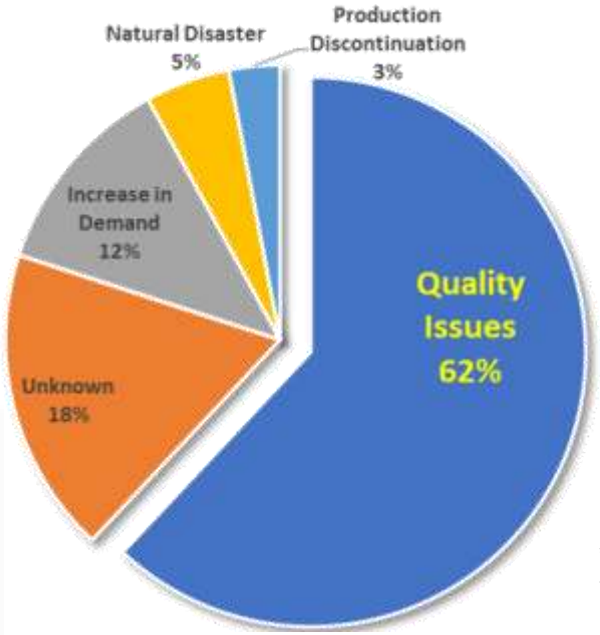
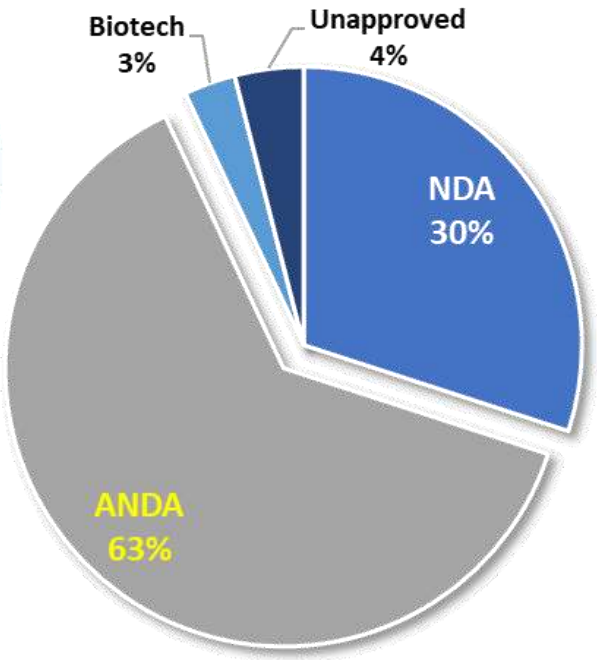
Drug Quality and Shortages



All Drugs Newly in Shortage



All Drug Products in Shortage

All Approved Generic Drug Applications

No Incentive for 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

An Enduring Solution: Quality Management Maturity

Product Quality

Every dose is safe and effective and free of contamination and defects

Gives patients confidence in every dose they **take**

Higher Confidence

Process Quality

Manufacturing risks controlled to provide quality drug product

Gives manufacturers confidence in every batch they **release**

Higher Confidence

Quality Management

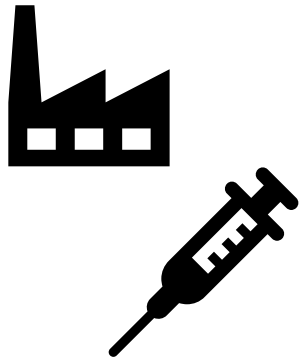
Performance and patient focus to identify areas of improvement and implement changes

Gives manufacturers confidence every batch will be **acceptable to release**

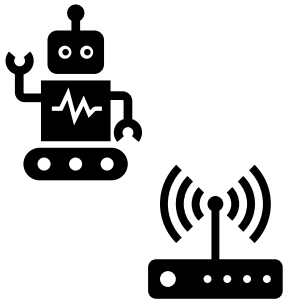
Lower Confidence

Future of Quality Management Maturity

- **A system to inform purchasers & patients about the quality management maturity of the facilities making their drugs**
  - Hear more from Alex Viehmann at 2:25AM



- **Embracing advanced manufacturing technologies in pharma**
  - Hear more from Sau (Larry) Lee at 4:25AM



Join Us in a Commitment to Quality

US FDA Center for Drug Evaluation and Research

WE WANT YOU

PAYORS

PURCHASERS

PROVIDERS

STUDENTS

COMPOUNDERS

REGULATORS

PATIENTS

CONSUMERS

TEACHERS

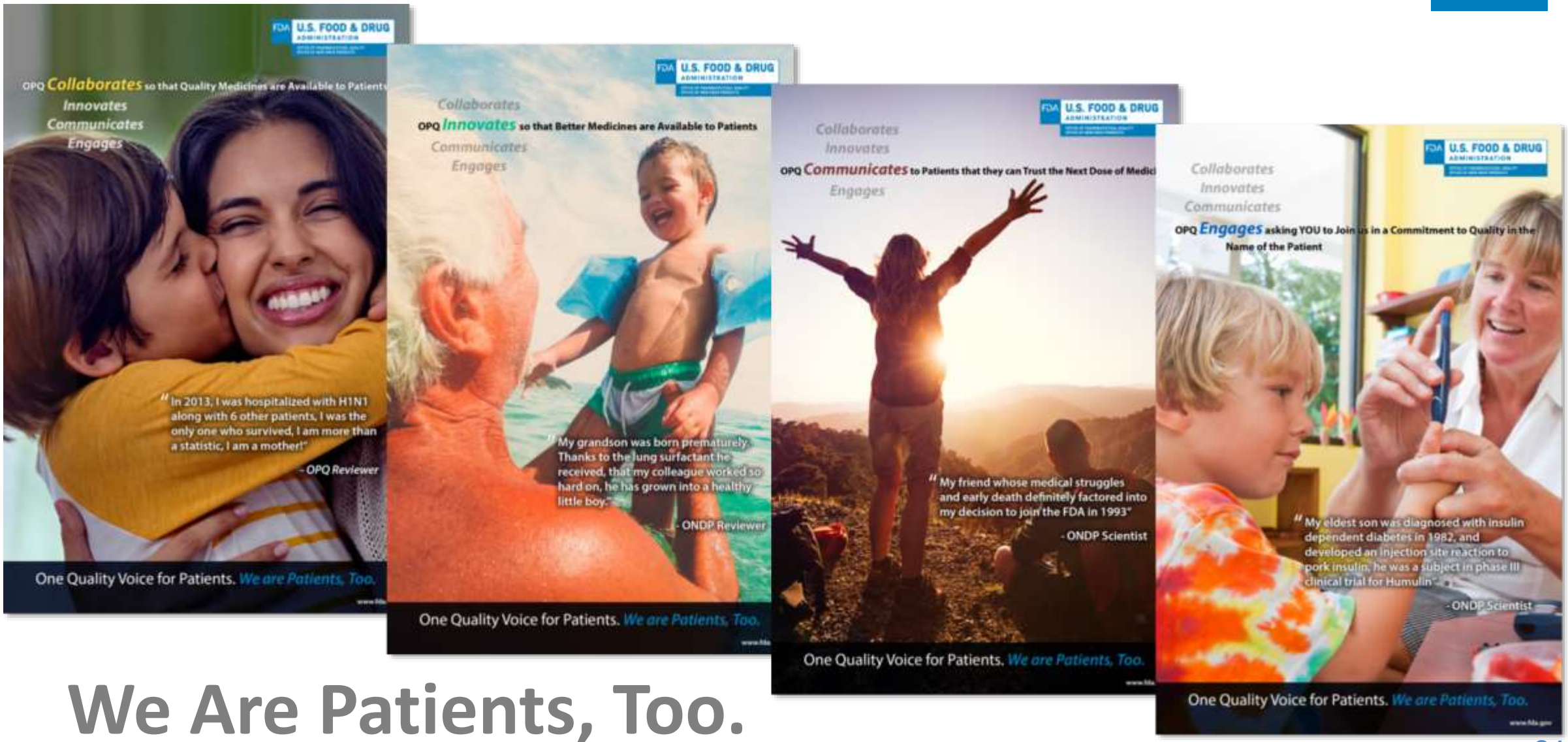
INTERNATIONAL

MANUFACTURERS

PHARMACISTS

HOSPITALS

One Quality Voice for Patients



We Are Patients, Too.

Let’s give us all *more* confidence in our *next* dose of medicine

FDA U.S. FOOD & DRUG ADMINISTRATION