



Global Expertise
Trusted Standards
Improved Health

USP Update

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USP MISSION

To improve global health through public standards and related programs that help ensure the quality, safety and benefit of medicines and foods.



Who We Are and Where We Work

- ▶ Founded in 1820, nonprofit, private, independent and self-funded
- ▶ Values-driven organization focused on quality standards to protect the public's health
- ▶ More than 1,000 employees worldwide

- ▶ Headquarters in Rockville, MD near Washington, DC, NIH and FDA
- ▶ Laboratory facilities in U.S., India, China, Brazil and Ghana
- ▶ Offices in Switzerland, Ethiopia, Indonesia, the Philippines and Nigeria

- ▶ Work with more than 900 scientists, practitioners and regulators to develop standards that help protect public health
- ▶ Internationally recognized and globally focused



We develop public, scientific quality standards
that help protect people's health

PHARMACEUTICALS

Nearly 200 years of
ensuring trust and
confidence among
patients and
providers



FOOD INGREDIENTS

Globalization means
food supplies today
face greater risks



HEALTHCARE QUALITY

Ongoing transformation
in health delivery
reveals additional needs
for standards setting



DIETARY SUPPLEMENTS & HERBAL MEDICINES

Explosive industry
growth demands a focus
on quality to ensure consumer
confidence and safety

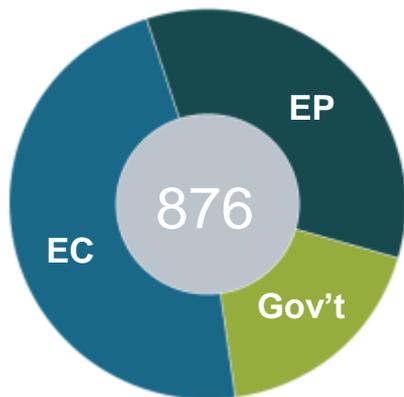


GLOBAL PUBLIC HEALTH

Combating substandard
and counterfeit medicines
in under-resourced
countries around the globe



The Experts Behind Our Standards



876 Scientific Experts— Volunteers and Government Liaisons

- 416 EC Members
- 301 EP-Only Members
- 159 Government Liaisons

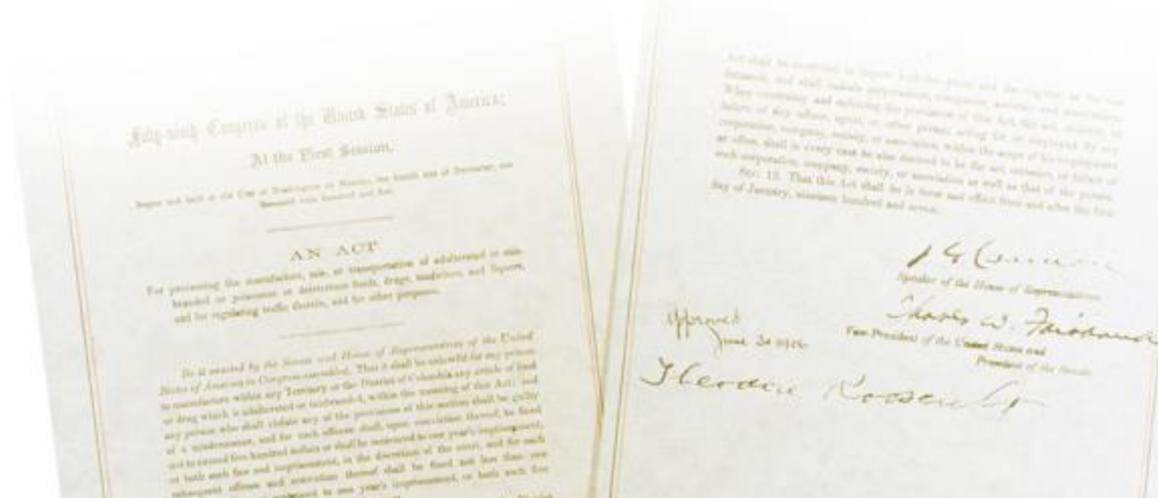
- ▶ Leaders in their respective fields in industry, academia, healthcare, regulatory affairs
- ▶ Together they contribute to standards development through Expert Committees and Expert Panels
- ▶ Government Liaisons also contribute to the process

Current Expert Committee Members By the Numbers



Role of USP Quality Standards in Law

- ▶ As an independent nonprofit organization, USP has shared a close relationship and collaborative history with FDA for more than a century
- ▶ USP's standards are recognized in U.S. law under the Federal Food, Drug, and Cosmetic Act (FDCA) since 1938
- ▶ Our work complements that of FDA and other government agencies at home and abroad, through our drug and biologic standards, dietary supplement standards, food ingredient standards, verification programs, and other activities around the globe



Our Work in Pharmaceuticals and Healthcare Quality

Pharmaceuticals (Rx, OTC)

- ▶ Our drug standards help ensure that patients worldwide have access to quality medications
- ▶ *United States Pharmacopeia–National Formulary (USP–NF)*

Healthcare Quality

- ▶ Our compounding standards help address healthcare practitioner and patient safety
- ▶ *USP Compounding Compendium*

- ▶ Medicare Model Guidelines

Physical Reference Standards

- ▶ More than 3,600 distributed worldwide



- ▶ USP develops standards and resources for all phases of product development, from raw material to market, which helps ensure patients receive quality biologic therapies
- ▶ Common biologics include injectable treatments for arthritis, blood clot prevention, medicines for cancer, diabetes, Crohn's disease, psoriasis, the Hepatitis B vaccine and pending stem cell therapies

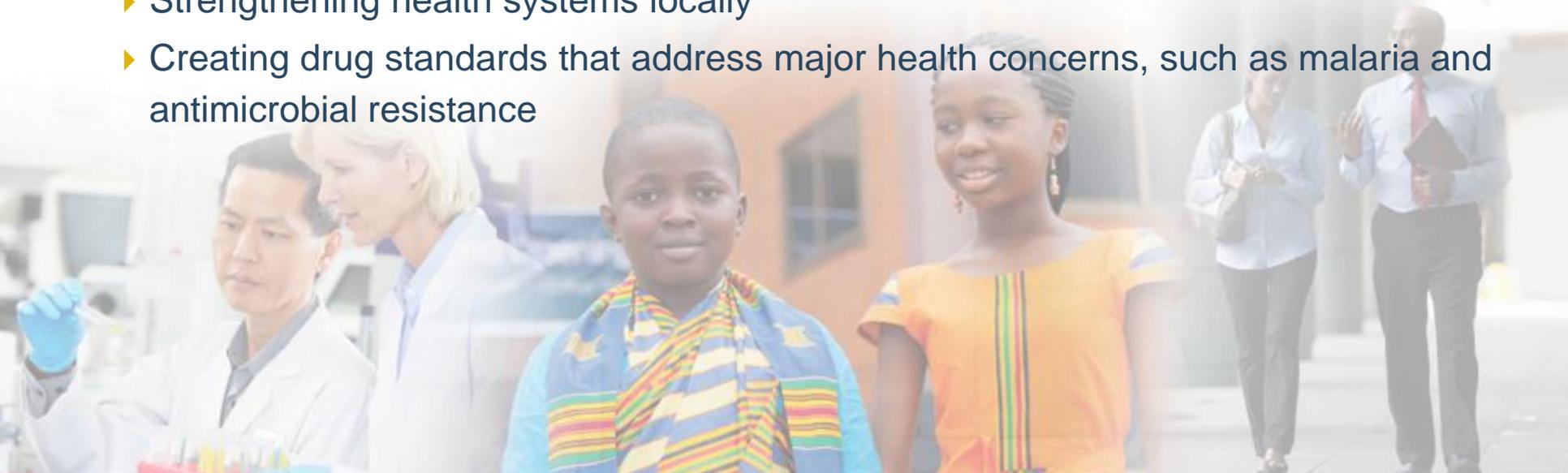


Our Global Public Health Reach

- ▶ We leverage our expertise in quality standards and supply chain integrity to build quality assurance capacity in under-resourced countries
- ▶ We manage field sites in Ethiopia, Ghana, Indonesia, Nigeria, and the Philippines, administer multiple programs funded by USAID, WHO and the Global Fund and deliver technical assistance and training to regulators and manufacturers in more than 70 countries

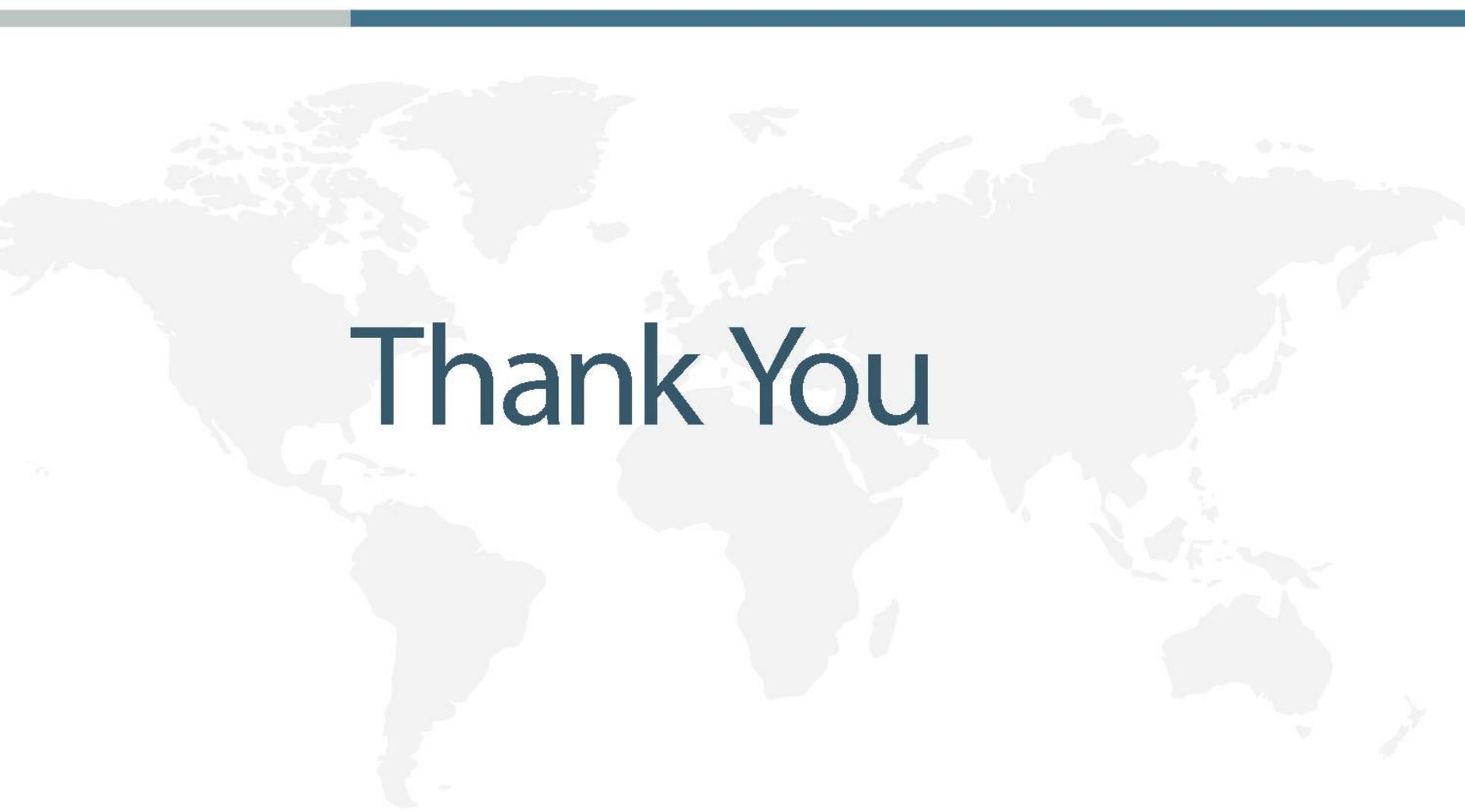
Areas of focus:

- ▶ Combating substandard and counterfeit medicines
- ▶ Strengthening health systems locally
- ▶ Creating drug standards that address major health concerns, such as malaria and antimicrobial resistance





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A light gray silhouette of a world map is centered in the background of the slide, showing the outlines of all continents.

Thank You