Advocating for Quality
to advance patient safety and public health

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Topics

- Key Facts about USP
- USP's Strategic Goals
- Today's USP Standards and Programs
- Building an Impactful Quality Standard
- Leaning in for better and more impact
- Compounding Update

About USP

We exist to …

- Protect patient safety
- Advance public health
- Foster competition for more affordable quality medicines

We are an 'organization of organizations'

- Governed by the USP Convention
- 450 academic institutions; healthcare practitioner, patient and industry groups; and governmental orgs

We are science-based

- Not-for-profit and independent

We are powered by …

- 900 experts from science and health who set USP quality standards
- 100 FDA staff participate in the process

- Founded in 1820
- 1,100 staff
- Laboratories in five countries
- Offices in eight countries
- US offices in Rockville & Frederick, MD & Washington, DC
- Standards recognized in law in 40 countries, utilized in 140

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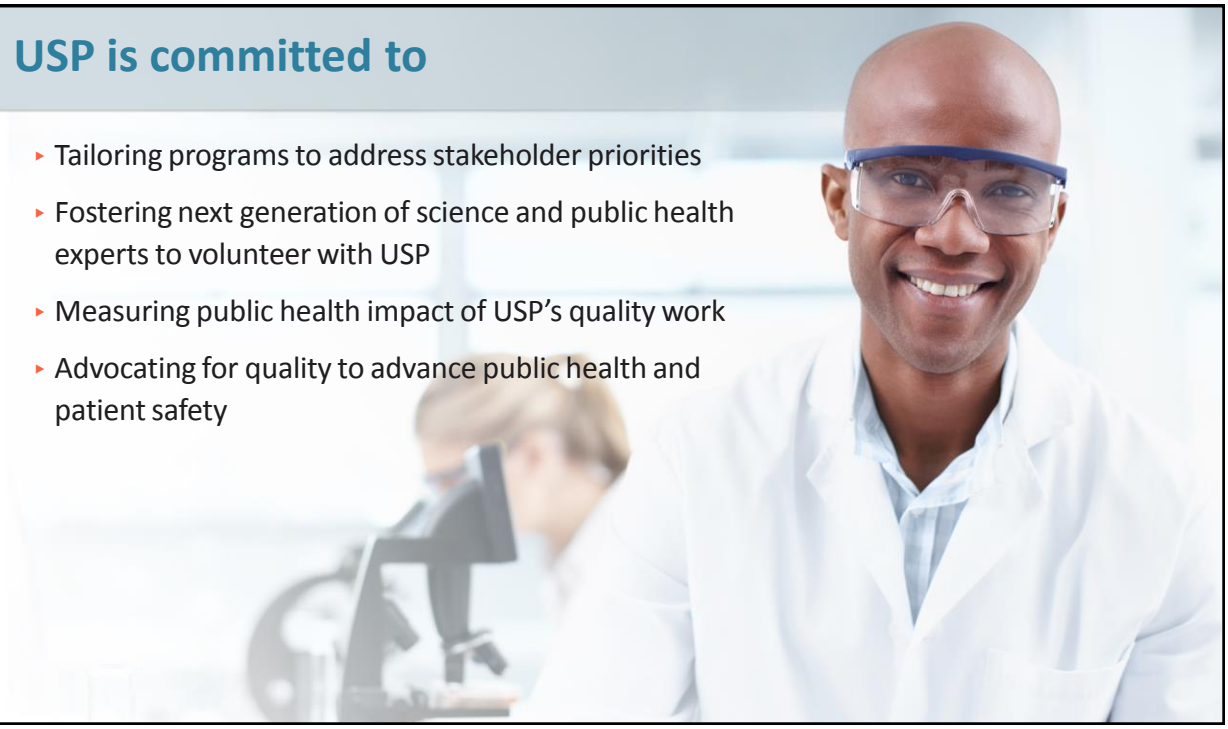
USP is committed to



- Tailoring programs to address stakeholder priorities
- Fostering next generation of science and public health experts to volunteer with USP
- Measuring public health impact of USP's quality work
- Advocating for quality to advance public health and patient safety

USP MISSION

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

- **Beyond standard setting**
- **Making an impact on public health and patient safety**

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From 1820, USP engaged to shape policy to advance quality

- 1902 Biologics Control Act
- 1906 Food and Drugs Act
- 1938 Food, Drugs and Cosmetics Act
- 1994 Dietary Supplement and Health and Education Act Biologics Control Act
- 2013 Drug Quality and Security Act

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Our programs have evolved to expand impact …

Quality Standards
- Standards for medical products, dietary supplements and food ingredients
- Standards for medication delivery and preparation

→ Developed through the USP Council of Experts and our Expert Committees, with FDA support and hundreds of pharmaceutical scientists and practice experts

Programs to fill critical regulatory gaps
- Verification for dietary supplements

→ Leverage public standards to provide assurance of GMP and conformance to standards

Tools for manufacturers & stakeholders
- Verification for excipients

→ Helping manufacturers and other to verify ingredient supply quality and avoid known risk

Regulatory Systems Strengthening

→ Working in LMIC to strengthen regulatory systems, partnering with USAID and donors implementation

Education and training

→ Engaging with industry and practitioners to help with implementation

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For Quality Standards to be impactful, they must be …

Aligned with
Public health and patient safety priorities

Developed by
Impartial, independent experts

Adapted & Improved
For technology and evolution of healthcare

Practical for
- Users of the standard
- Enforcers of the standard

Measured by
Public health impact indicators

Informed by
Real world implications for patients and practitioners

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Pharmacists' critical role in quality

- Experts in standards development committees
- Patient counseling on medicines
- Patient education on dietary supplements, foods and OTCs
- Compounding

- Initiating development: USP Medicine Quality Curriculum for schools of pharmacy

Leaning In … for Better and More Impact

Partnering in Coalitions

Giving Quality a Voice in Policy Dialogue

Payment Systems

- Provider Status
- Link between implementation of standards and payment

Data Expectations

Leveraging standards for impact in crisis situations

- Opioids

Taking a Stand on Issues Core to Quality

- Importation

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Coalition Engagement

- **Creating and leading forums** where we can bring others together
- **Joining** where we can make an important contribution
- **Lending support** to help enable key stakeholders to advance quality, consistent with our mission

If you're in a coalition and you're comfortable, you know it's not a broad enough coalition.

Bernice Johnson Reagon

DSQC Dietary Supplements Quality Collaborative

Prescriptions for a Healthy America

"A Partnership for Advancing Medication Adherence"

Pharmacists Care

ASOP Global | Alliance for Safe Online Pharmacies

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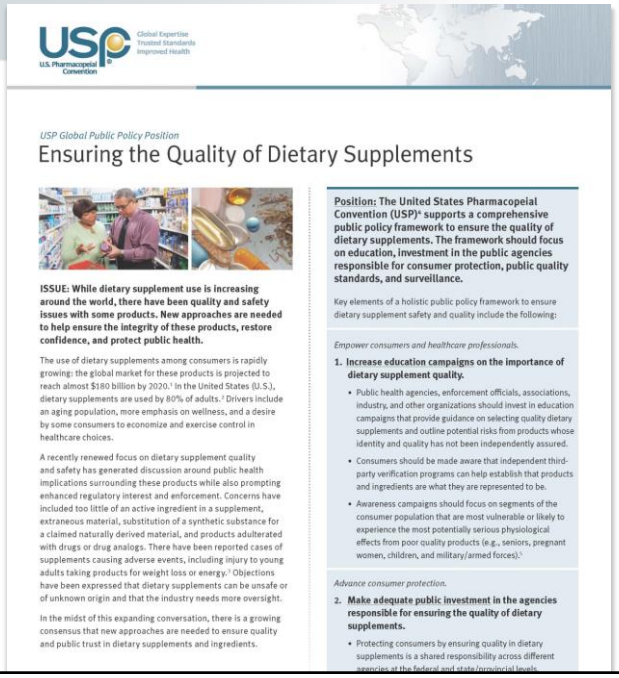
Public Policy Dialogue

Seeking holistic approaches

Framing quality within the broader public policy framework

- ✓ *Ensuring Dietary Supplement Quality*
- ✓ *Reducing Falsified and Sub-standard Medicines*
- ✓ *Advancing Safer Compounding*
- ✓ *Controlling AMR*



USP U.S. Pharmacopeial Convention — Global Expertise Trusted Standards Improved Health

USP Global Public Policy Position

Ensuring the Quality of Dietary Supplements

ISSUE: While dietary supplement use is increasing around the world, there have been quality and safety issues with some products. New approaches are needed to help ensure the integrity of these products, restore confidence, and protect public health.

The use of dietary supplements among consumers is rapidly growing: the global market for these products is projected to reach almost $180 billion by 2020.[1] In the United States (U.S.), dietary supplements are used by 80% of adults.[2] Drivers include an aging population, more emphasis on wellness, and a desire by some consumers to economize and exercise control in healthcare choices.

A recently renewed focus on dietary supplement quality and safety has generated discussion around public health implications surrounding these products while also prompting enhanced regulatory interest and enforcement. Concerns have included too little of an active ingredient in a supplement, extraneous material, substitution of a synthetic substance for a claimed naturally derived material, and products adulterated with drugs or drug analogs. There have been reported cases of supplements causing adverse events, including injury to young adults taking products for weight loss or energy.[3] Objections have been expressed that dietary supplements can be unsafe or of unknown origin and that the industry needs more oversight.

In the midst of this expanding conversation, there is a growing consensus that new approaches are needed to ensure quality and public trust in dietary supplements and ingredients.

Position: The United States Pharmacopeial Convention (USP)[4] supports a comprehensive public policy framework to ensure the quality of dietary supplements. The framework should focus on education, investment in the public agencies responsible for consumer protection, public quality standards, and surveillance.

Key elements of a holistic public policy framework to ensure dietary supplement safety and quality include the following:

Empower consumers and healthcare professionals.

1. **Increase education campaigns on the importance of dietary supplement quality.**
   - Public health agencies, enforcement officials, associations, industry, and other organizations should invest in education campaigns that provide guidance on selecting quality dietary supplements and outline potential risks from products whose identity and quality has not been independently assured.
   - Consumers should be made aware that independent third-party verification programs can help establish that products and ingredients are what they are represented to be.
   - Awareness campaigns should focus on segments of the consumer population that are most vulnerable or likely to experience the most potentially serious physiological effects from poor quality products (e.g., seniors, pregnant women, children, and military/armed forces).[5]

Advance consumer protection.

2. **Make adequate public investment in the agencies responsible for ensuring the quality of dietary supplements.**
   - Protecting consumers by ensuring quality in dietary supplements is a shared responsibility across different agencies at the federal and state/provincial levels.

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Mindful of the practical factors
that facilitate implementation of standards

- **Pharmacy practitioners**
  - For better outcomes and patient literacy
  - Cognitive services including counseling where questions on quality are implicated
- **Reimbursement to drive health systems**
  - CMS Conditions of Participation
- **Rational payment for practitioners**
  - Investments of time and for equipment
- **Common cause with partners**

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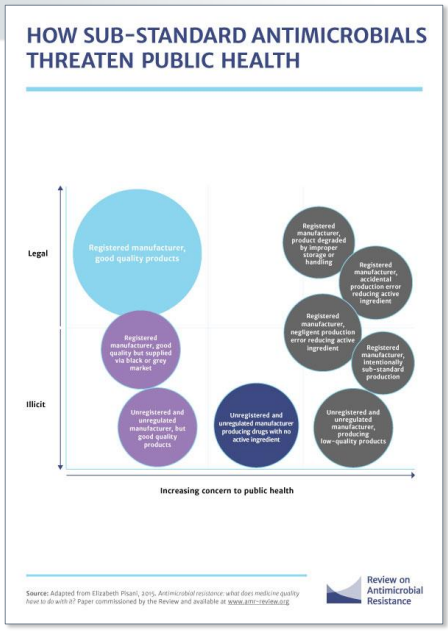
The Data Imperative

- **Macro-data gaps on medicine quality**

  Such as …
  - Cost of poor quality
  - Benefits of good quality
  - Substandard medicine impact on antimicrobial resistance
- **The new "USP Quality Institute"**
  - Research fellows to develop evidence on topics
  - Informed and interpreted by high-level advisory group
  - Initial focus on AMR
  - Lead but also contribute to broader conversations



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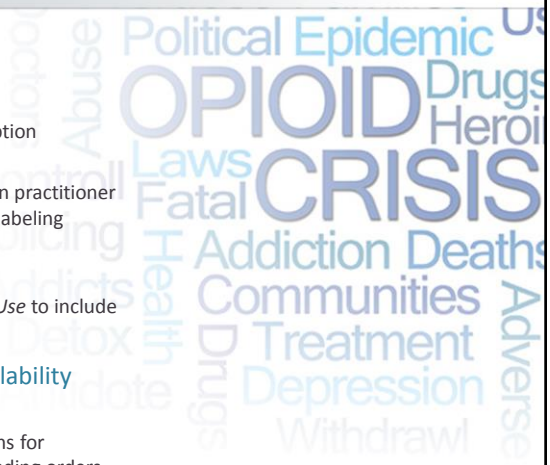
New Approaches to Leverage Standards

to Help Address Today's Public Health Issues

For example, the opioids addiction crisis:

- **Improve patient literacy on risk of addiction**
  - **Prescription container labels:** Modify General Chapter <17> Prescription Container Labeling standards
  - **Pharmacist counseling:** Create new informational General Chapter on practitioner counseling with subsection on opioids and references to disposal and labeling
- **Proper disposal of unused opioids**
  - Modify <1066> *Physical Environments That Promote Safe Medication Use* to include language on the safe removal of unused opioids
- **Naloxone:** Advance efforts to facilitate access and OTC availability
  - Develop new USP naloxone drug product monographs
  - Develop consumer-directed labeling standards for naloxone instructions for prescription products that are distributed "OTC" pursuant to state standing orders
- **Tools to communicate with patients**
  - Public service announcements: Offered to pharmacists and other practitioners to share with patients



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Taking a Stand on Issues Core to Quality

THE HILL

Drug importation from Canada increases patient risk with no guarantee of lower prices

BY RONALD T. PIERVINCENZI, OPINION CONTRIBUTOR - 03/31/17 05:20 PM EDT

© Getty Images

Drug pricing is once again being debated in Washington and in state capitals. One of the proposals on the table – importation of medicines from Canada – poses dangerous patient risks. This proposal is intended to reduce the price Americans pay for medicines. But the risks to patient

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Compounding

Revision Update

- **Sterile Compounding (USP chapter 797)**
  - Will be released for another public comment period
  - Over 9000 comments received and under review
- **Continuous Engagement**
  - Broad range of stakeholders
  - Federal and state regulators

Our Approach

- **Risk-based**
  - Focus on improving quality in areas of greatest risk to patients
- **Strive for standard that is:**
  - Implementable and implemented
  - Enforceable and enforced
  - Effective and impactful

Protect Patients ◆ Preserve Practice ◆ Maintain Access

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