Enhancing Consumer Confidence in Dietary Supplement Quality through

Transparent Standards &
Quality Verification Programs

Anthony Lakavage, J.D.
Senior Vice President, Global External Affairs

Panel on Nutritional Supplements
CWAG 2017 Chair’s Initiative and Western Pacific AG Summit

March 15, 2017
About USP

• We exist to ...
  ✓ Protect patient safety
  ✓ Advance public health
  ✓ Foster the affordability of 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

• 1,100 staff
• Laboratories in four countries
• Offices in eight countries
• Standards recognized in law in 40 countries, utilized in 140

Founded in 1820
PHARMACEUTICALS
Nearly 200 years of ensuring trust and confidence among patients and providers
- Chemical Medicines
- Biologics
- Excipients

FOOD INGREDIENTS
Globalization means food supplies today face greater risks
- Food Chemicals Codex
- Food Fraud Database
- Technical Assistance/Training

HEALTHCARE QUALITY
Ongoing transformation in health delivery reveals additional needs for standards setting
- Patient Safety
- Healthcare Worker Safety
- Formulary Development Guidelines

DIETARY SUPPLEMENTS & HERBAL MEDICINES
Explosive industry growth demands a focus on quality to ensure consumer confidence and safety
- Reference Standards
- USP Verified

GLOBAL PUBLIC HEALTH
Combating substandard and counterfeit medicines in under-resourced countries around the globe
- USAID Quality Medicines
- Regulatory Technical Assistance

Standard Setting
Monographs
Reference Standards
Training
Industry
Regulators
Reg Systems Strengthening
Surveillance
Lab accreditation
Advocating for Quality
Awareness
Policy engagement
Evidence generation

Global Expertise  |  Trusted Standards  |  Improved Health
COPYRIGHT 2015. ALL RIGHTS RESERVED.
Regulatory framework for supplements quality

- Treated as foods in the U.S.
- USP quality standards are official but not required
  - If a manufacturer states USP compliance, FDA can enforce against them
- Manufacturers may set their own standards, however, these are not always public and transparent

Market forces and state of the industry

- FDA inspects for compliance with Good Manufacturing Processes (GMP)
  - Nearly 60% of inspected firms cited for GMP violations (2015):
    - 16% → failure to verify identity of ingredient in an appropriate test
    - 19% → failure to set specs on identity, purity, strength, composition
- Serious problem of bad actors
- Consumer awareness growing
- Market forces encouraging quality
  - More companies utilizing transparent standards and verification programs
Programs to Advance Supplement Quality

- Dietary Supplement Quality Standards
- Dietary Supplement Quality Verification
- Dietary Supplements/Adulteration Database
- Dietary Supplements Quality Collaborative

Confirming quality
Identifying risks
Harnessing a community
Components of a Public Quality Standard

Monograph
Values to establish:
- Identity
- Potency
- Purity

Analytical tests to assess value

Packaging and labeling

General Chapters
Establish procedures, methods, and practices related to testing and quality parameters

Reference Standard
Highly-characterized physical specimens of the ingredient, excipients, and impurities

Utilized by manufacturers to calibrate testing and to ensure their products meet specifications in a monograph or General Chapter
Standards Offer a Transparent Assurance of Quality

- Established and revised by independent experts
- Development process includes input from any interested stakeholders
- New standards/updates with input from industry, stakeholders, FDA, anyone
- Available to ANYONE for manufacturing, product development, compliance
USP Verification Services

- Voluntary – manufacturer decision
- Verifies supplement quality based on
  - Public standards
  - Manufacturer specifications
  - Good Manufacturing Practices
- 700 million bottles carry label
  - But, this is < 1% of supplements

USP Dietary Supplement Verification
Launched 2002

USP GMP Facility Audit Program
Launched 2015
The USP Verified Mark on the label indicates:

- **What’s on the label is in the bottle** (and what’s not isn’t)
- Declared potency and amounts
- No harmful levels of specified contaminants and/or adulterants
- Product will break down in the body within a specified amount of time
- Manufactured using safe, sanitary and well-controlled practices

The USP Verified Mark does not indicate:

- Efficacy
- Clinical safety issues
  - Drug interaction
  - Dosing
  - other
Key Elements of Verification Program

1. Product appropriate for inclusion in program

2. Audit of manufacturing sites for GMP compliance

3. Review of chemistry, manufacturing and controls product documentation

4. Laboratory testing of product samples

5. Review of conformance with mark usage guidelines

6. Continuous surveillance:
   - Surveillance audits
   - Internal audit report,
   - Annual product report
   - Product testing

Phase I

Phase II

Mark Approval
Quality is *the* leading differentiator to consumers

- Quality is #1 driver for dietary supplement purchases (national survey)
- Over ¾ of consumers consult healthcare practitioners on recommended supplements
- More than ½ of consumers look for an independent quality seal or mark

- Verified supplements significantly outperform the market
  - One leading brand of verified supplements outperforms in annual year-on-year sales (+9.2%) compared to all brands combined (+5.5%)

- Verification is **more important than price** once consumers understand its meaning
Adulterants Database

- Tool to focus stakeholders on issues regarding adulterants and tainted dietary supplements, across the supply chain, around the world

- Informed by
  - Enforcement reports from multiple agencies
  - Literature research

- Useful for
  - Private sector
  - Consumer orgs
  - Law enforcement

- Planned launch in 2018
Harnessing the Community

Convening stakeholders to

- Identify risks in the quality framework
- Highlight best practices
- Seek consensus
- Dialogue with decision makers

Twenty Five stakeholder groups participating

- Policy think tanks
- Industry
- Healthcare Practitioners
- Patients
- Other standards organizations
To sum up....

- Lots of tools for responsible manufacturers to ensure consumers of quality
- Consumers are beginning to demand quality
- But, still disincentives to adhere to public standards, and only 1% of supplements utilize transparent verification programs
- Partnering with stakeholders to encourage best practice and shine a light on those putting patients at risk is essential for public health