

USP Virtual Symposium

Emerging technologies

in **probiotic, live biotherapeutic product** and
microbiome analysis

Oct. 6-7, 8:30-11:30am ET



Opening Remarks, USP Overview

Kit Goldman, Ph.D. | October 6, 2022





Mission

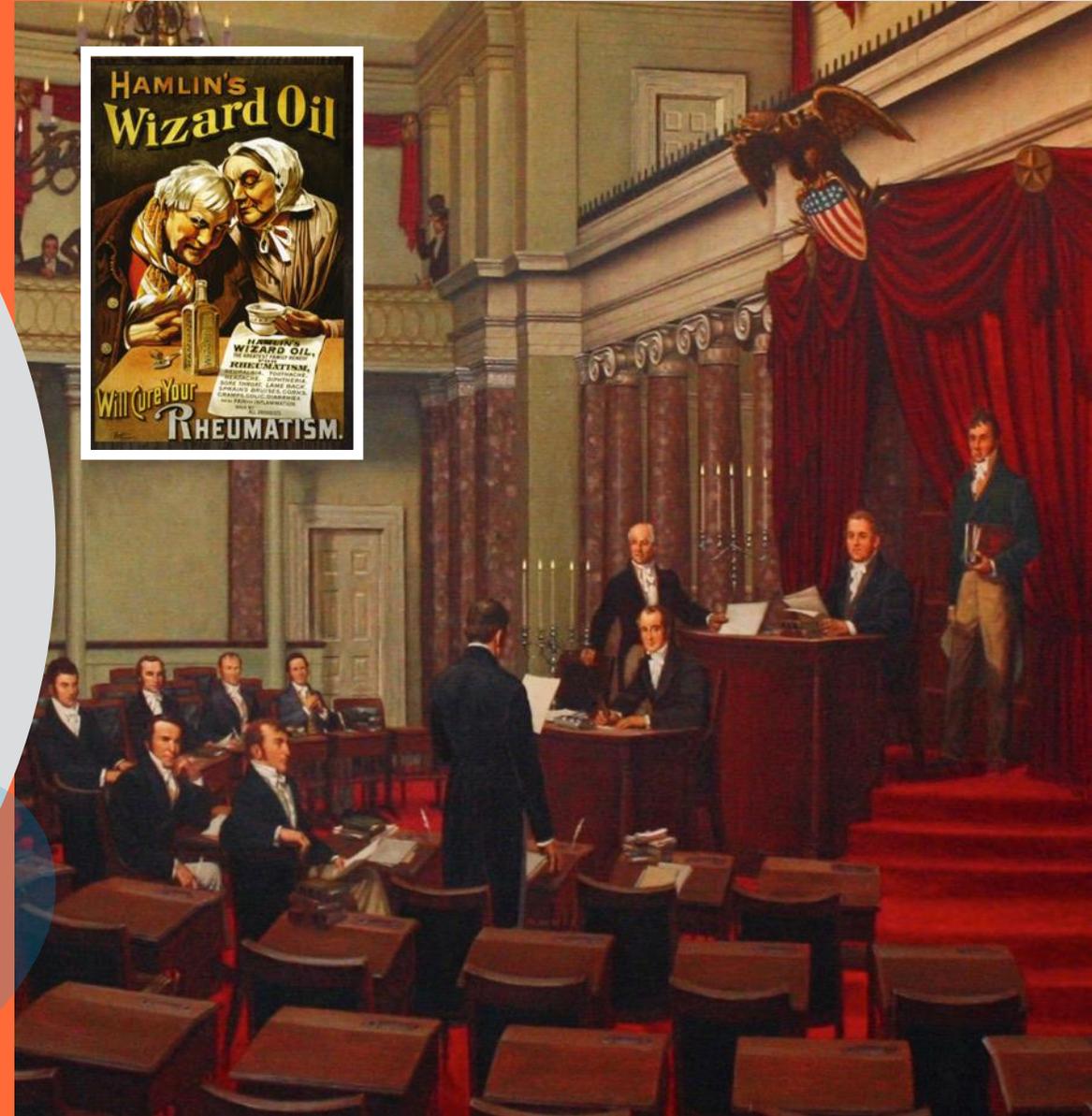
To improve global health through public standards and related programs that help ensure the quality, safety and benefit of medicines and foods



Our enduring mission



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



The Value of Public Standards



- ▶ Provides scientific basis for decision making
- ▶ Ensures a consistent approach to quality
- ▶ Useful for monitoring of counterfeit and substandard products and quality



- ▶ Appropriate titles
- ▶ Useful definitions
- ▶ Validated methods
- ▶ Established limits



- ▶ Address quality attributes and acceptance criteria through monograph specifications
 - Definition: characteristics of the probiotic ingredient or dosage form (genus, species, strain)
 - Identity: Identification by targeted PCR with specific primers (state of the art at this time)
 - Strength: enumeration (CFU/g)
 - Contaminants: indicator and specified microorganisms
 - Additional requirements - Storage and Labeling
- ▶ ***Meet GMP requirements for specifications - identity, strength, purity, composition, limits on contaminants***

USP Probiotics Expert Panel Membership



Name	Member	Affiliation
Sanders, Mary Ellen	Chair	ISAPP
Schoeni, Jean	Vice-Chair	USP-NBDS
Elkins, Chris	Government Liaison	CDC
Dreher-Lesnicks, Sheila	Government Liaison	FDA
Tartera, Carmen	Government Liaison	FDA
Boyte, Marie-Eve	Member	
Burguiere, Pierre	Member	AMA Research Solutions
Jackson, Scott	Member	NIST
Keller, David	Member	Keller Consulting
Pane, Marco	Member	Probiotal Healthcare
Larsen, Marianne	Member	Christian Hansen
Stahl, Buffy	Member	IFF
Vegge, Christina	Member	Christian Hansen
Brooks, James	EC	USP-NBDS
Bradley, Mike	EC	USP-NBDS
Roe, Amy	EC	USP-DSAEL

Practical Concerns: Strain Identification and Enumeration



- ▶ Identification of strain by ingredient supplier and product manufacturer should be the same
- ▶ Correct identification of strain in finished product
- ▶ Identification of strains in multi-strain materials
- ▶ Identification of microbial contaminants
- ▶ Variability in enumeration (CFU method)
- ▶ Stability of strains – large overages used
- ▶ Need for quick, inexpensive, reliable methods

Thank You



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Stay Connected

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Thank You



Empowering a healthy tomorrow