

What Works



NCCAM Colloquium **EXPLORING OPPORTUNITIES** **FOR COLLABORATION WITH** **INDUSTRY**

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Three Principal Areas of Need

- # What Works
- # What Makes What Works Work
- # How Best to Determine What Works

What Works

- # Host of relevant targets
 - Top Ten Products in Terms of Sales
 - Top Prospects Based on "Evidence" in Existence
 - Exploration of Potential Targets
- # Host of relevant opportunities
 - Universities Have Interest
 - Industry Has Interest

Look At the Evidence

- # Studies from Foreign Sources
 - China has a Wealth of Data
 - Europe is the Most Well Known
 - Do Not Discount Native American Knowledge
- # Studies of Lesser Quality
 - Less Than the Gold Standard
- # Anecdotal Reportage
 - Traditional Medicine Practitioners

Evidentiary Presentation

- # Anticipate Support from Single Companies
 - Competition Dictates
 - Look to Support Shared Science
- # Anticipate Generation of Data for Product Classes
 - Liquid Presentations
 - Single Entities (a focus)

Why Does It Work

- # Look at the Materials We Know or Believe Offer Clear Benefit
- # Investigate the composition
- # Understand that compositional issues exist
 - Do Not Fall Directly to Ehrlich
 - Twist The Point of View
 - Saw Palmetto Example

Identify Then Determine

- # Once Identified, the materials must become better known
- # Analytical methodologies
- # Non-standard approaches
 - Vitamin C
 - Any Botanical

Determine Then Publish

- # Making available the results of the work
- # Making mandatory the determinations of the data
- # Understanding the application is Industry's Job
- # Support for Compendial Presentation
 - USP/NF
 - AHP
 - Any P or F

The Techniques Must Be Refined

- # Refinement does not truly mean specificity
- # Refinement does not necessarily mean hypericin
 - Reality is Marketing is a Key Player in the Mix
- # Science leading into multiple determinations is essential

Allow Those With Best Knowledge to Apply Them

- # Turn Again to Qualified Labs
- # Certification of the Labs Themselves
- # Identification of University Affiliations Are Beneficial
- # Anticipate Broad Results and Data Spread
- # Listen To All Presentations

How To Know What Works

- # Our Current Lock In to the Gold Standard
 - Solid for Single Chemical Entities
 - Entire Industry Exists because of it
- # Works Well Until . . .
 - Effects are Subtle
 - Effects are single and don't necessarily drive "Side Effects"

What Works In A Revised Model

- # Ascertain the methods applied in Europe as a Beginning
- # Gather the Best Minds on the Topic To Discuss
- # Post Ideation, take the designs to the Regulators
- # Refine the Model and Apply It for Accurate Determination
- # Look for Inclusion of Traditional Applications with Results

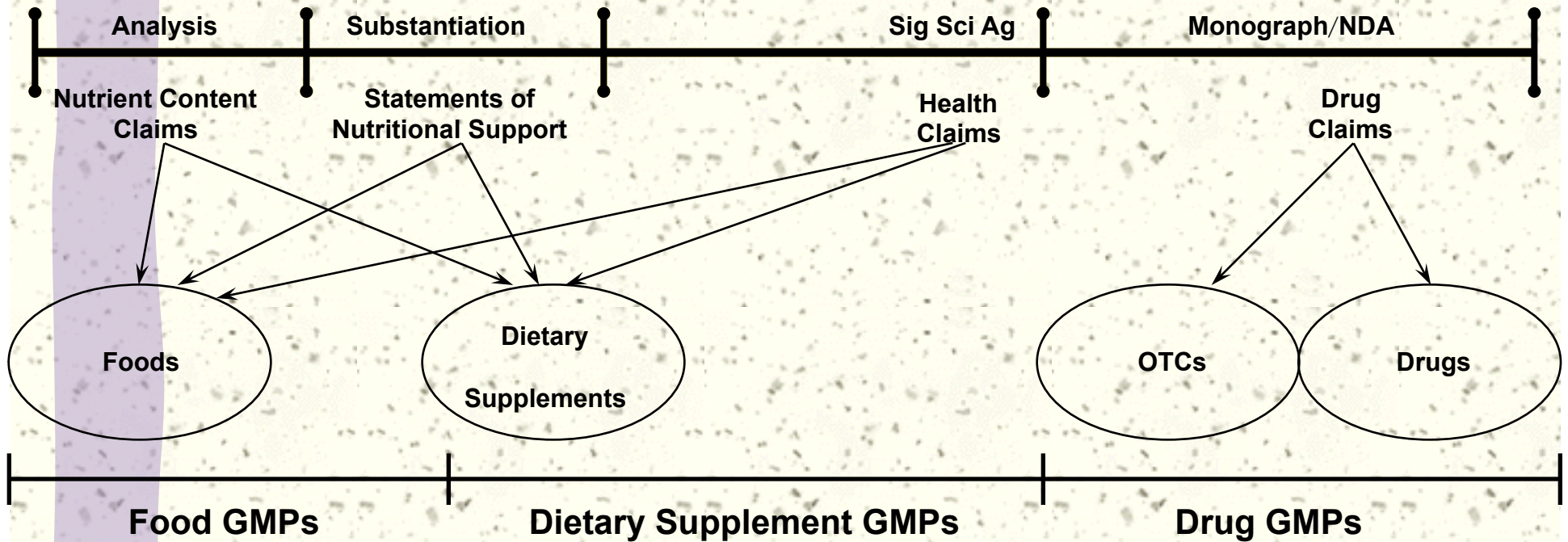
Support From NCCAM

- # Focus on the Initiatives that vary from the current Norm
- # Focus on Initiatives with Broad Industry Support
- # Do Not Neglect the Perceived Outliers

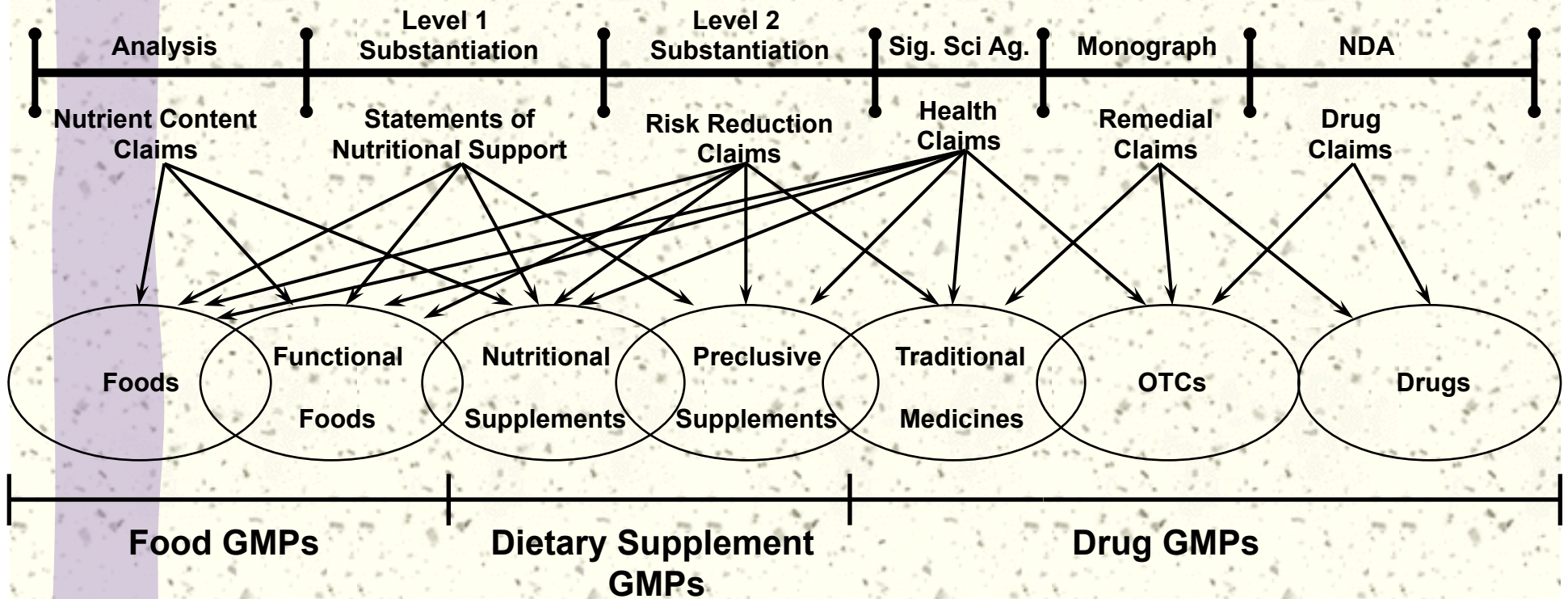
Ultimate Impact ON Regulatory Model

- # Establish a Continuum of Claims Categories
- # Supported by Consistent Production
- # Determined by Substantiation Requirements out of NCCAM Support
- # Apply the Results of the NCCAM Supported Findings both to the Support and the Substantiation

The Regulatory Continuum



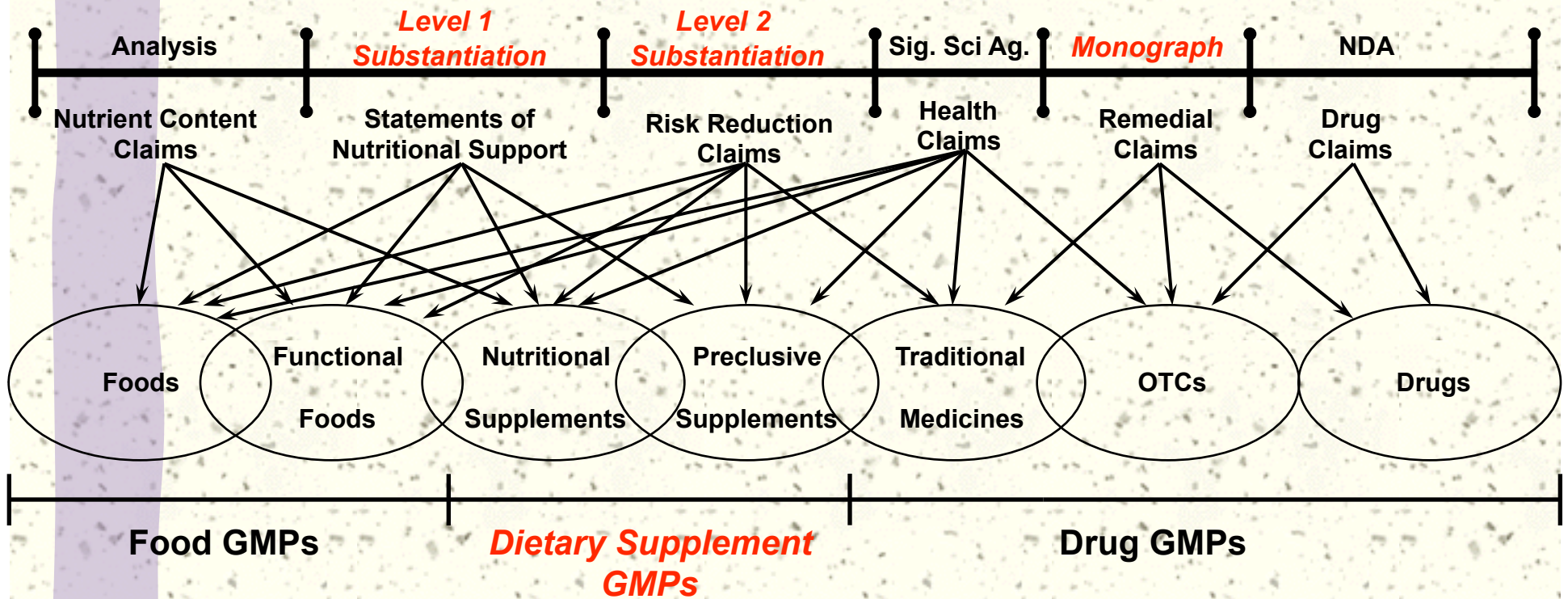
The Regulatory Continuum



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The Regulatory Continuum



The Future.

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