CONGRESSWOMAN

DIANA HARSHBARGER

PROUDLY SERVING TENNESSEE'S FIRST

DIETARY SUPPLEMENT INNOVATION ACT

BACKGROUND

For more than thirty years, the *Food, Drug, and Cosmetic Act's* drug preclusion provisions have created regulatory uncertainty for dietary supplement and drug manufacturers alike. Drug preclusion authorizes the FDA to prohibit an ingredient, first approved as a drug or subject to clinical drug investigations, from being sold as a dietary supplement. In practice, the FDA can declare dietary supplements illegal even if they have been on the shelves for years.

The current system, built on ambiguous standards, allows for drug preclusion for ingredients filed under a confidential Investigational New Drug application. Similarly, some ingredients remain precluded from dietary supplement innovation, even after the drug manufacturer has abandoned its investigation. This system discourages investment in dietary supplement innovation and limits consumer access to lawful products.

THE SOLUTION

The *Dietary Supplement Innovation Act* modernizes drug preclusion rules by establishing clear standards for when preclusion applies, protecting longstanding dietary supplement ingredients, and creating a transparent process for FDA determinations and review.

WHAT THE BILL DOES

- **Protects grandfathered ingredients:** Preserves ingredients that were marketed in food or dietary supplements before relevant drug approval or clinical development milestones.
- **Ends perpetual preclusion:** Allows preclusion to expire when Phase 2 or 3 clinical investigations have been inactive or withdrawn for at least seven years, or when drug development has been publicly discontinued.
- **Creates FDA exception authority:** Allows FDA to approve the use of an otherwise precluded drug or biological product in food or dietary supplements through an administrative order.
- **Establishes science-based standards:** Requires FDA to consider differences in route of administration, dosage, concentration or composition, and safety when determining whether a drug and dietary supplement contain the same "article."
- **Provides judicial review:** Makes FDA warnings and other statements asserting a violation of drug preclusion immediately reviewable by a court and places the burden of proof on the federal government.

BOTTOM LINE

The *Dietary Supplement Innovation Act* will establish transparency and predictability within the drug preclusion framework while preserving pharmaceutical innovation and consumer access to dietary supplements.