



VENABLE

**Opportunity for Expanding Health Related
Claims in the Practitioner Channel
NBJ Summit**

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Third-Party Literature

- Publications (articles, book chapters, or official abstracts of peer-reviewed scientific publications) written by third parties about the health benefits of a dietary supplement may be distributed under certain circumstances in connection with the sale of supplements to consumers
- Third-party literature is not considered labeling if:
 - Truthful and nonmisleading
 - PhyPublications (articles, book chapters, or official abstracts of peer-reviewed scientific publications) written by third parties about the health benefits of a dietary supplement may be distributed under certain circumstances in connection with the sale of supplements to consumers
 - Separate from the product it describes
 - Presents a balanced view of available scientific information about the supplement and its health benefits
 - Does not mention the name of a manufacturer or the brand name of a product
- FDA construes narrowly – May consider it to be evidence of intended use



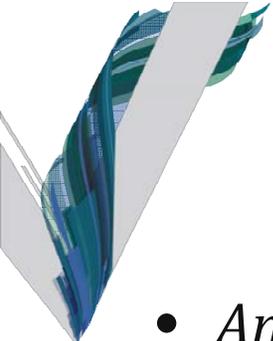
Third-Party Literature

- Considerations:
 - Does the literature explicitly state or imply that the product can be used to prevent, treat, or mitigate any disease?
 - Does the literature constitute labeling for the product?
 - Physician office
 - Password protected website
 - Medical Conference
 - Educational Webinar
 - Company Sponsored Conference



Websites

- Separation of editorial content and third-party literature from the portions of website selling products
 - Don't crosslink
 - No mention of or link to specific products in editorial content
- “Two-Click Rule” no more
- Use of password protected sites for healthcare professionals
 - Pros: Allows more control over who views the information; provides more separation between portions of the website where products are sold and the portions containing third party literature
 - FDA has in the past gained access behind password protected portion of website to access content



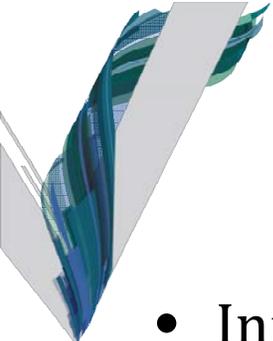
Amarin – Potential Opportunity

- *Amarin Pharma v. United States Food & Drug Administration et al.*, 15-cv-3588 (PEU) (S.D.N.Y. August 7, 2015).
 - Prescription drug company shared materials and study results with doctors the described off-label endpoints for their drug
 - Threatened misbranding action by FDA claiming that the product is misbranded due to off-label promotion
 - Amarin filed for preliminary injunction, claiming First Amendment protected speech
 - Court ruled in favor of Amarin finding that FDA was barred by the First Amendment from bringing a misbranding action over truthful and non-misleading speech



Implications of Amarin

- What are the limitations of *Amarin*?
- How does a case involving prescription drugs translate to dietary supplements and other FDA regulated products?
- What would FDA's reaction be if companies begin to extensively rely on *Amarin*?



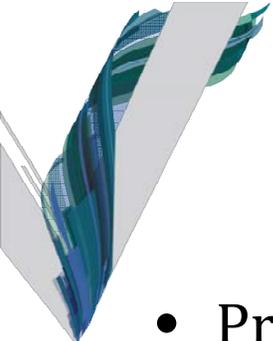
Application of Amarin to Practitioner Channel

- Information only provided to health care providers, not consumers
- Claims do not constitute labeling and are not subject to FDA jurisdiction
- Practice of medicine (if it is the doctor providing the information to their patients)
- First Amendment protection of truthful, non-misleading commercial speech



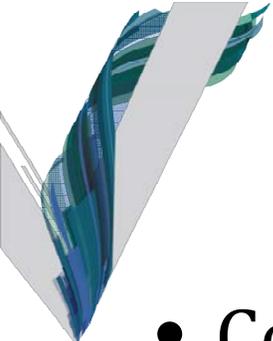
Forging a New Path

- Paradigm Shift
 - Recognize the difference between aging and disease
 - Recognize the difference between consumer based products and products offered by physicians
 - Permit the communication of all truthful and nonmisleading benefits of dietary supplements and other functional products to healthcare practitioners
 - Permit the use of Healthcare Savings Accounts for the purchase of dietary supplements
 - Medical Foods
 - Legislation



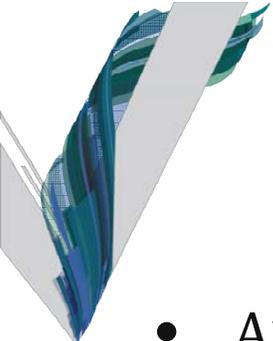
Medical Foods

- Pros of marketing a product as a Medical Food:
 - FDA premarket approval not required
 - Express disease management claims
 - Less costly to manufacture
 - Less regulatory oversight
 - FDA objects may be able to rebrand as a dietary supplement or conventional food with appropriate structure/function claims



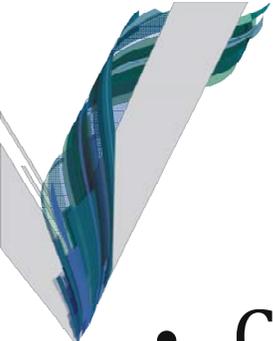
Medical Foods

- Cons of the Medical Food approach:
 - Extensive amount of R&D time
 - Requires at least Significant Scientific Agreement
 - Clinical studies are costly and reliance on 3rd-party literature is questionable
 - Category narrowly construed



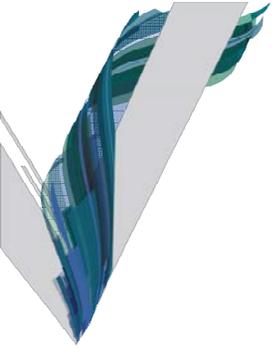
Legislation

- Approaches to consider:
 - Company registration, product listing of products, and providing promotional material with FDA
 - Create a monograph system or clearance system for practitioner products
 - Permit the use of Healthcare Savings Accounts for the purchase of dietary supplements
 - Address state anti-kickback laws that place the healthcare practitioner at risk for selling dietary supplements out of their office



Legislation

- **Costs to Investigate Legislation**
 - To determine whether there is political will the initial cost of a legislative effort would cost between \$10k to \$15k per month for 1 to 3 months to identify champions and determine whether there is a political will
 - This effort would include
 - Drafting a white paper
 - Drafting legislation
 - Meetings with key members of the House and Senate



Questions

