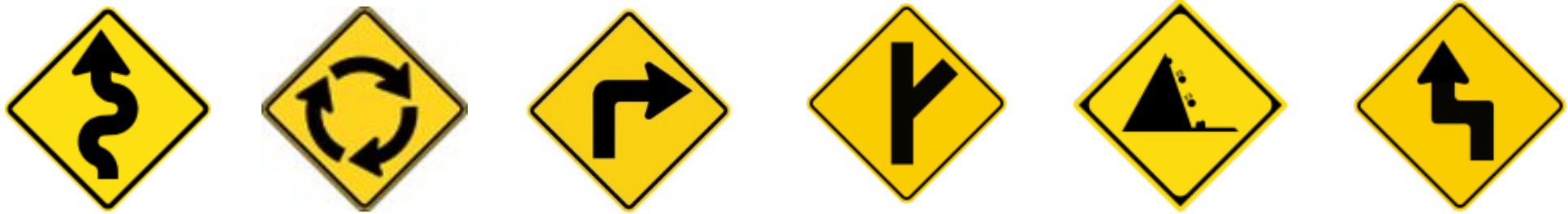
What's Ahead for DSHEA Reform?

Proposals for Revisions to the Industry's Foundational Law



Summary: Here is what's on the table

1. Mandatory product listing
2. The gap in the definition of dietary supplements
3. A legal pathway for CBD
4. Addressing the drug preclusion provision more broadly
5. Authorizing GMP inspections by third party auditors
6. Dissemination of scientific information / claims proximity to labels and products

1. Mandatory Product Listing

- FDA cannot properly regulate what it can't see--FDA lacks visibility into the breadth and variety of the supplement marketplace.
- Would require all products marketed as dietary supplements to be listed with FDA and give FDA authority to act against noncompliant products.
- Would allow FDA to know when new products are introduced, quickly identify and act against dangerous or otherwise illegal products and improve transparency to promote risk-based regulation.
- The manufacturer, packer, or distributer whose name appears on the label of a dietary supplement offered for sale in the United States would be required to file a notification of that product with the FDA when it enters the market along with a copy of the label.

MPL – Progress to date

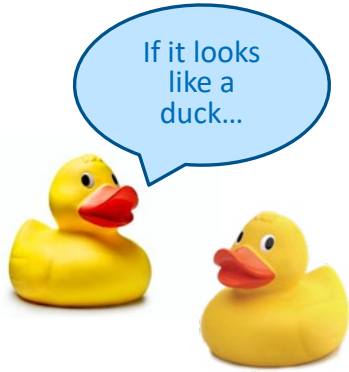
- CRN invited to the negotiations by Sen. Durbin; MPL is the only item he is interested in.
- Being at the negotiation table has allowed industry to extensively shape the legislation. Our mantra: *"A birth certificate; not a drivers license."*
- Extensive discussions have helped frame the bill and push back on FDA and CSPI efforts to expand the scope of what must be provided to FDA.
- When the Durbin bill is introduced, it "locks in" FDA as to what it will accept. If MPL is part of a broader DSHEA reform agenda, this piece is already completed.

2. Addressing the Gap in Dietary Ingredients

- Most product categories regulated by FDA are defined by their intended use.
  - A drug means articles intended to diagnose, cure, mitigate, treat, or prevent disease.
  - A cosmetic is an article intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance.
- But a dietary supplement is an article intended to supplement the diet AND must contain a dietary ingredient (as enumerated in the law).
- FDA's view is that if doesn't contain a dietary ingredient, it's not a dietary supplement.

Addressing the Gap (cont.)

- FDA's position had led to a gap in enforcement for many products that are marketed as a dietary supplement but contain only unapproved drugs or illicit substances—FDA says they are not supplements so they can't be prosecuted as supplements, and CDER doesn't place a high priority on prosecuting them as unapproved new drugs.
- Solution: Clarify that products marketed as supplements may be regulated as supplements; illegally marketing a product as a dietary supplement is a prohibited act. Adds import exclusion and seizure authorities too.



3. A Legal Pathway for CBD in Dietary Supplements

- Despite passage of the 2018 Farm Bill that removed “hemp” from the CSA, FDA insists that hemp-derived products containing CBD are not permitted to be sold as dietary supplements.
- FDA’s position is that the drug preclusion provision of DSHEA excludes CBD from supplements because CBD was first marketed as a drug (while hemp was still a controlled substance).
- Separately FDA raises questions about the safety of CBD and refuses to grant an exception by regulation for CBD because it says it doesn’t have enough safety data to make a decision.
- Solution: HR 841 – provides a legislative exception to the drug preclusion provision and requires CBD products to be regulated as dietary supplements.
- CRN opposes granting FDA authority to set a pre-market maximum safe level for CBD.

Drug Preclusion Provision – 21 USC 321(ff)(3)(B)

(ff)The term "dietary supplement"—

(3) does —

(B) not include—

(i) an article that is approved as a new drug under section 355 of this title, certified as an antibiotic under section 357 of this title, or licensed as a biologic under section 262 of title 42, or

(ii) an article authorized for investigation as a new drug, antibiotic, or biological for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public,

which was not before such approval, certification, licensing, or authorization marketed as a dietary supplement or as a food unless the Secretary, in the Secretary's discretion, has issued a regulation, after notice and comment, finding that the article would be lawful under this chapter.

4. The Drug Preclusion Clause

Clarifying the Extent of the Drug Preclusion Provision

- What is the "article" in §321(ff)? Is it specific to the exact ingredient used in the drug?
- Does a different delivery form count? What about dosage? What about a different therapeutic use?
- Was DSHEA intended to be retroactive—can FDA cite the drug preclusion provision to remove from the market a previously grandfathered ingredient?
- If FDA has previously allows an article to be used in supplements, can it subsequently remove the article on these grounds ?
- When should FDA use its discretion to override the general rule?
- What does it mean to find that "the article would be lawful under this chapter"? Is this a backdoor to a premarket safety evaluation?

Addressing the Lack of GMP Inspections

- GMPs, mandated by DSHEA, are critical to assuring safe, quality dietary supplements.
  - 21 CFR Part 111 have fully enforceable since 2010.
- FDA is hopelessly behind in conducting GMP inspections.
  - Each year, FDA inspects less than 5% of registered DS facilities.
- Private third party auditors are capable of inspecting firms against these requirements and could make their findings public if FDA authorized firms to use third party inspectors.
- This would allow FDA to prioritize its resources based on risk, and would allow firms to demonstrate their compliance with GMPs.

5. Authorizing Third Party Inspections

- Directs FDA to accredit third party organizations to conduct GMP inspections for DS facilities
- Either FDA or individual establishments can request these third-party inspections be conducted.
- FDA must develop general criteria for accreditation and provide a public registry of accredited organizations (e.g., NSF, USP, UL, Eurofins).
- Third parties have the authority of FDA during an inspection.
- Inspections are paid for by FDA (if FDA requests) or by the establishment (if it requests).

Traditional View of Claims Proximity

(a) A publication, including an article, a chapter in a book, or an official abstract of a peer-reviewed scientific publication that appears in an article and was prepared by the author or the editors of the publication, which is reprinted in its entirety, shall not be defined as labeling when used in connection with the sale of a dietary supplement to consumers when it—

(1) is not false or misleading;

(2) does not promote a particular manufacturer or brand of a dietary supplement;

(3) is displayed or presented, or is displayed or presented with other such items on the same subject matter, so as to present a balanced view of the available scientific information on a dietary supplement;

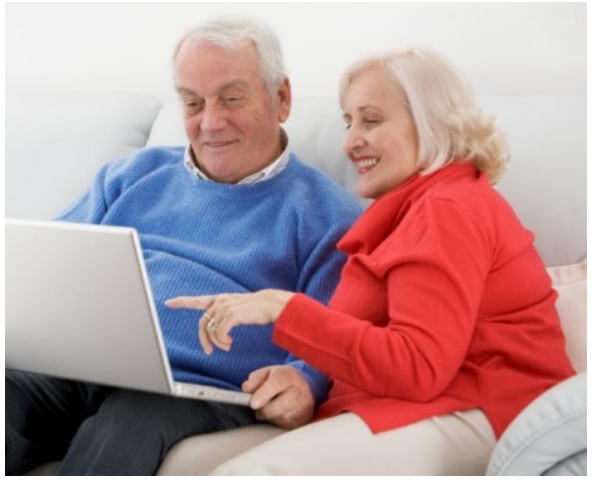
(4) if displayed in an establishment, is physically separate from the dietary supplements; and

(5) does not have appended to it any information by sticker or any other method.

21 USC §343-2

Claims Proximity in an Internet Age

- How do marketers communicate truthful scientific information about their dietary ingredients?
- Can websites/social media affiliated with marketers provide truthful scientific information about the benefits of their products that go beyond S/F claims?
- As drug companies “disease-ify” conditions that were once considered to be life stages and conditions of normal living, where is the line between S/F claims and claims to prevent, treat, cure or mitigate disease?



6. Dissemination of scientific information

- Solution: Remove the physical proximity provision from DSHEA
- Clarify what is a “claim” to exclude the presentation of scientific studies even on commercial websites and social media postings if the studies are published, peer-reviewed and presented in their entirety in an objective manner.
- Also exclude such presentations as evidence that the product is intended to be a drug.

Trade Association Positions

	CRN	AHPA	UNPA	CHPA	NPA
1. Mandatory Listing	Support	No position*	Support	Support	Oppose
2. Gap in Dietary Supplement Defn	Support	Undecided	Supports	Supports	?
3. Pathway for CBD	Support	Support	Supports	Supports	Support*
4. Revise Drug Preclusion	Support	Supports*	Supports*	Supports*	?
5. Deputizing Third party inspections	Support	Unknown	Supports	Supports	?
6. Dissemination of Science / claims	Support	Supports	Supports	Supports	?

Council for Responsible Nutrition

The Science Behind the Supplements

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