DSHEA 2.0 Mandatory Product Listing and Other Potential Changes Under Discussion

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Outline

- 25 Years DSHEA; where it all began
- Dietary Supplement Innovation Initiative
  - FDA's plans and actions
- DSHEA 2.0
  - FDA
  - Industry
  - Regulation-Minded Consumer Groups

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25 Years DSHEA

A Success Story?

DSHEA Revolutionized the Supplement Industry

- For over three decades FDA had been limiting the marketing of supplements, including:
  - In 1962, attempts to set minimum/maximum levels for supplements
  - 1966-1973: efforts to classify vitamins with more than 150% of RDI as drugs – Proxmire Amendments
  - 1993: attempts to ban black currant oil through a food additive theory.

- DSHEA: Purpose was assuring widespread consumer access to natural health products and protection of public safety from charlatans, deliberate adulterations, and reckless introduction of unsafe products.

- In 1994, the industry was worth $4 billion. In 2019, it was estimated to be worth over $40 billion; more than 75% of consumers use dietary supplements, more than 9000 DS facilities.

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Developments since 1994

- FALCPA
- (Serious) adverse event reporting for dietary supplements
- Mandatory recall authority for foods
- Food Safety Modernization Act (FSVP, intentional adulteration, etc.)
- Amendment of section 413
- The law has evolved and shown to provide flexibility to address issues that arise.

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FDA Concerns

- Industry large and diverse (is that a problem?)
- Spiked Supplements
- Lack of New Dietary Ingredient Notifications (NDINs)
- Continuing issues with compliance with 21 C.F.R. Part 111
- These concerns (if valid) can be addressed without statutory amendments

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Dietary Supplement Innovation Initiative

FDA's Plans for Modernization

- In February 2019, then Commissioner Gottlieb issued a statement laying out FDA's thoughts/plans to modernize regulation of dietary supplements.
- FDA priorities:
  - Ensure safety; protect consumers from harmful products
  - Maintain product integrity: ensure that dietary supplements contain the ingredients that they are labeled to contain, and nothing else, and that those products are consistently manufactured according to quality standards
  - Informed decision-making; foster an environment where consumers and health care professionals are able to make informed decisions before recommending, purchasing or using dietary supplements

FDA Initiatives to Improve Oversight

- Rapid response tool: Dr. Gottlieb mentioned that the Agency has developed a rapid-response tool to alert the public when a supplement contains an illegal ingredient or poses a health risk but did not provide further details.
- Update of FDA's policies regarding New Dietary Ingredient Notifications (NDINs): FDA believes the number of NDINs submitted is too low. Even if only 10% of the supplements on the market contain NDIs, the number of NDINs should be 4 to 5 times as high.
- Creation of a Botanical Safety Consortium, a public-private partnership with the goal of providing appropriate tools to evaluate the safety of botanical ingredients
- Enforcement actions against unlawful claims and ingredients and develop new enforcement strategies
- Modernization of DSHEA…

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FDA

FDA initiatives included proposals that would require amendment of the law.

- Mandatory Product Registration
- FDA hinted that exclusivity for New Dietary Ingredients which are subjects of NDINs could function as a reward to companies for submission of an NDIN.

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Mandatory Registration; A Fix for What?

- Transparency: the Agency cannot regulate what it "cannot see"
- Track dangerous products
- Identify new dietary ingredients
- Monitor trends

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Current Mandatory Product Listing

- Listing requirements already exist for medical devices and drugs
- No review or approval of listings
- Few enforcement actions re failure to list (except for imports)
- No evidence that FDA monitors, tracks, etc. listings
- Small companies need (paid) help with listing
- The public and foreign entities tend to read an approval in the listing

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Burdens of Mandatory Listing for Supplements

- A given firm may have to list 100s or 1,000s or even more products
- Routine updating for new products, discontinued products, and label changes; timing of update? (Product no longer manufactured, no longer sold?)
- Requirement to label products with an FDA-assigned identification number (or other methods to track changes)?
- Commercial impacts for FDA delays in updating the public-facing database?
- Availability of information on contract-manufacturing relationships?
- Potential complexities of coordination across own-label distributors, contract packers, and contract manufacturers

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Mandatory Registration; Will it Fix the Problem?

- What if bad actors do not register? (How will FDA know where to find the bad actors?)
- What will be the penalty for failure to register?
- Will labels disclose spiking?
- Will FDA enforce registration/listing requirement?

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FDA's Other Issue; NDINs

- Companies do not submit NDINs when needed.
- FDA hints at exclusivity as incentive.

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Should There be More NDINs?

- Two exceptions to NDIN requirement:
  - ODI (grandfathered ingredients). There is no list of ODIs.
  - The dietary ingredient is an NDI that has been present in the food supply (no geographic limitation) as an article used for food in a form in which the food has not been chemically altered.
    - FDA has limited food supply to conventional foods.
      - But a dietary supplement is a food!
    - FDA broadly interprets "chemical alteration"
    - Change in manufacturing causes an ingredient to be an NDI subject to NDIN?
- In any case, the marketers of a dietary supplement must have a reasonable basis that the product is safe for its intended use.
- FDA's interpretation would result in very large number of NDINs. Does this benefit public health?

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Incentives for NDIN Submission

- Are they needed?
- Should there be exclusivity for a dietary ingredient? (Supplements are foods.)
- Who would manage exclusivity? Costs?
- FDA currently has no authority to grant exclusivity.
- Will the market benefit from exclusivity, or will exclusivity result in disputes about protection of an ingredient? Aren't there other forms of IP protection (patents)?
- Duration of exclusivity?
- How will this benefit consumer access?
- FDA's priority is safety and public health.

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DSHEA 2.0: industry wish list?

What Will Industry Get (or Want?) if the law will be amended (in Exchange for Mandatory Listing)?

- Master files
- CBD
- Clarity on meaning for 201(ff)(1)(E): "a dietary substance for use by man to supplement the diet by increasing the total dietary intake"
- Revision exclusionary clause provisions 201(ff); 301(ll)? How?

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- Pandora's box; be careful what you ask for.

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Wish List Regulation-Minded Consumer Groups

- Premarket Safety Review: Close the (secret) GRAS loophole
- Bolster adverse event reporting. Report all AEs
- Premarket review of known dangerous products
- Labeling of supplement-drug interactions
- Mandatory recall authority (already exists)
- Criminal penalties (already exist)
- Etc. etc.

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Thoughts

- FDA must focus on safety.
- No grand scale overhaul of the law seems required. Industry and consumers will be better served by enforcement of regulations (and law) that do exist.
- Need more certainty and consistency regarding interpretation; Some “problems” originate from FDA interpretation and inconsistent (or no) enforcement.
- FDA should enforce the existing law to punish those that do not comply; enforcement against non-compliance rewards those that comply.
- Misunderstanding about safety of dietary supplements; a solution looking for a problem? There will always be bad actors.
- Interpret section 201(ff)(1)(E) broadly to stimulate innovation
- FDA should recognize that dietary supplements are foods. (Therefore, inclusion of a substance into a dietary supplement constitutes presence in the food supply.)
- FDA needs additional resources.
- Industry can help by self-regulation, developing certification programs that are consistent with the regulations and with each other. Customers can require certifications re GMP compliance (annual audits); customers can “enforce” NDIN requirement.

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Questions