The State of the Supplement Industry

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Nutrition Business Journal Reports

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State of the Supplements Industry
Expo West 2018

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2017 supplement market overview – growth remains steady at 6.1%, reaching $43.5B

Supplement Sales and Growth

Supplement Market Share, 2017e

Source: Nutrition Business Journal (2017 preliminary estimates; $mil, consumer sales)
2017 Industry trends

- Fuel (Gut, Protein, Energy)
- Beauty-from-within
- Head games
- CBD
- Pill fatigue
- Changing retail landscape
Focus on Fuel
Protein supplements gain momentum – both in and out of the gym

**Powders**

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<tr>
<td>Sales ($mil)</td>
<td>4000</td>
<td>5000</td>
<td>6000</td>
<td>7000</td>
<td>8000</td>
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<td>10000</td>
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**Beverages**

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<td>Sales ($mil)</td>
<td>200</td>
<td>400</td>
<td>600</td>
<td>800</td>
<td>1000</td>
<td>1200</td>
<td>1400</td>
<td>1600</td>
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</table>

Source: Nutrition Business Journal (2017 preliminary estimates; $mil, consumer sales)
Gut Health – probiotics growth slows, but consumers gain interest in prebiotics and digestive enzymes

Source: Nutrition Business Journal (2017 preliminary estimates; $mil, consumer sales)
Consistent increase in growth rate for energy supplements, reaching $1.8B in 2017
Beauty-from-within
Natural and organic personal care growth slows as interest in beauty-from-within grows

Source: Nutrition Business Journal (2017 preliminary estimates; $mil, consumer sales)
Hair, Skin and Nails Supplements – collagen is the category’s hot ingredient

Sales grew 7.2% to $1.1B

By Ingredient, 2017

Source: Nutrition Business Journal (2017 preliminary estimates; $mil, consumer sales)
Collagen continues double-digit growth

U.S. Collagen Supplements sales grew 30% to $98M in 2017

Source: Nutrition Business Journal (2017 preliminary estimates; $mil, consumer sales)
Head Games
Cognitive health growth spikes to 6.2% in 2017 – addressing memory, focus

Source: Nutrition Business Journal (2017 preliminary estimates; $mil, consumer sales)
Supplements targeting mood, stress, and anxiety increase growth to 5.9% - adaptogenic herbs boom

Source: Nutrition Business Journal (2017 preliminary estimates; $mil, consumer sales)
Growth projections in vision supplements spike above 6% as blue light becomes a focus

Source: *Nutrition Business Journal* (2017 preliminary estimates; $mil, consumer sales)
CBD
Expo West CBD Summit takeaways

U.S. Hemp-Based CBD Product Sales

- Everybody’s getting in on it
- Everybody still has questions
- Full-spectrum industrial hemp-derived CBD, NOT isolates
- Disease claims and other supplement rules are still a problem
- Legislation can make or break the category

Source: Hemp Business Journal ($mil, consumer sales)
Pill Fatigue
Pill fatigue drives growth of non-pill formats, such as gummies, powders, and liquids

Source: Nutrition Business Journal (2017 preliminary estimates; $mil, consumer sales)
Pill fatigue drives innovation in novel delivery formats
Changing retail landscape
Natural and specialty leads supplements market share

Growth by channel

Market share by channel, 2017e

Source: Nutrition Business Journal (2017 preliminary estimates; $mil, consumer sales)
Top five channels by 2017 growth
Survey of Branded Supplement Manufacturers

1. E-Commerce – Third Party
2. E-Commerce – Company Website
3. Natural
4. Dietary Supplement
5. Specialty

Source: New Hope Network survey conducted Q1 2018 (N=136)
35% of surveyed branded supplement manufacturers think brick and mortar will not be at all important in 5 years.

Source: New Hope Network survey conducted Q1 2018 (N=155), All Manufacturer Results
Question: How would you rate the importance of each channel over the next five years?
Get 20% OFF NBJ’s 2017 Supplement Business Report

Promo code: EXPOWSUP
Valid 3/3/18-3/31/18
William Hood & Company is a differentiated industry-focused investment banking practice covering the Consumer, Food and Retail sectors with a specialization in health & wellness and other current consumer trends.

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Hands on, Senior Level Execution

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We are a purpose-built team passionate about the health and wellness industry.

Our insight-driven and authentic approach is custom designed to develop and communicate the unique strengths of each of our clients’ businesses.

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William Hood  
Managing Director  
20 Years Wall Street

Jill Staib  
Director  
14 Years Industry

Margot Reutter  
Vice President  
14 Years Industry

Supported by a team of Associates and Analysts
Our Industry Focus is Consumer, Food and Retail with an Emphasis on the Convergence of Healthy Living Macro-trends with the Largest Consumer Categories.

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- Food & Beverage
- Beauty, Personal Care & Consumer Health

- Millennials
- Digital First
- Direct to Consumer
- Natural and Organic
- Transparency
- Globalization
We Have a Leading Track Record in Nutrition

Transactions represent William Hood & Company principals’ involvement at WHC and at prior firms
Our Most Important Transaction of 2018
‘Tainted Dietary Supplements Frequently Hit The Market’

"The dietary supplement market is a dangerous Wild West of inadequate regulation" that deprives consumers "of basic health and safety information" and results "in serious injuries and deaths."

‘Orrin Hatch is leaving the Senate, but his deadliest law will live on’

“Hatch introduced DSHEA in collaboration with then-Sen. Tom Harkin (D-Iowa), but there was no doubt that it was chiefly his baby. The act all but eliminated government regulation of the dietary and herbal supplements industry.”

-- LA Times, Michael Hiltzik, Jan. 5, 2018
FDA cGMPs—a Decade Later

- FY17 inspections: 656
- Number of inspections issued a 483: 379 (58%)
- Average number of observations per 483: 5.14
- Number of OAI (official action indicated) inspections: 39
- OAI inspections of large firms: 0

Source: Natural Products INSIDER Freedom of Information Act (FOIA) request to FDA
Top Three cGMP Citations

Failure to establish product specifications for identity, purity, strength and composition of finished dietary supplement

• 89 inspections (23.48% of inspections w/ 483)

Failure to establish/follow written procedures for quality control operations

• 70 inspections (18.47%)

Failure to establish/follow written procedures for requirements to review and investigate a product complaint

• 63 inspections (16.62%)

Source: INSIDER FOIA Request to FDA
<table>
<thead>
<tr>
<th>Dietary Supplement cGMP Subpart</th>
<th>% of Observations</th>
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<tbody>
<tr>
<td>B—Personnel</td>
<td>3.0</td>
</tr>
<tr>
<td>C—Physical Plant and Grounds</td>
<td>4.3</td>
</tr>
<tr>
<td>D—Equipment and Utensils</td>
<td>4.6</td>
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<tr>
<td>E—Requirement to Establish a Production and Process Control System (PPCS)</td>
<td>33.9</td>
</tr>
<tr>
<td>F—PPCS: Requirements for Quality Control</td>
<td>10.8</td>
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<tr>
<td>G—PPCS: Requirements for Components, Packaging, and Labels and for Product That You Receive for Packaging or Labeling as a Dietary Supplement</td>
<td>3.4</td>
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<tr>
<td>H—PPCS: Requirements for the Master Manufacturing Record</td>
<td>8.9</td>
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<tr>
<td>I—PPCS: Requirements for the Batch Production Record</td>
<td>8.1</td>
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<tr>
<td>J—PPCS: Requirements for Laboratory Operations</td>
<td>1.6</td>
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<tr>
<td>K—PPCS: Requirements for Manufacturing Operations</td>
<td>1.4</td>
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<tr>
<td>L—PPCS: Requirements for Packaging and Labeling Operations</td>
<td>2.2</td>
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<tr>
<td>M—Holding and Distributing</td>
<td>6.5</td>
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<tr>
<td>N—Returned Dietary Supplements</td>
<td>4.6</td>
</tr>
<tr>
<td>O—Product Complaints</td>
<td>6.1</td>
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<tr>
<td>P—Records and Recordkeeping</td>
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NDI Notifications (NDINs)

FY17 NDINs received: 102
Responses: 101
Acknowledgements w/out objection: 13%
Inadequate safety/identity: 20%
Incomplete notification: 40%
Not dietary ingredient/dietary supplement: 28%

Source: FDA
Pre-NDIN Meeting With FDA

“In our experience, [NDI] submissions are more likely to receive a positive outcome when potential notifiers take advantage of the opportunity to meet with us before they have prepared a submission, and we will continue to work with notifiers during and after the submission to answer unresolved questions.”

Source: FDA spokesperson via email
FDA’s Authority

- Warning Letters
- Regulatory Meetings
- Seizure of products
- Injunctions
- Criminal Prosecutions
Seizure of DMAA

2013: FDA detains millions of dollars in DMAA (1,3-dimethylamylamine) from Hi-Tech Pharmaceuticals Inc.

• Hi-Tech sues government under Administrative Procedure Act
• Government files suit for forfeiture

2017: Federal judge rules in favor of FDA/DOJ on summary judgment

• DMAA not dietary ingredient or GRAS (generally recognized as safe)
• Following ruling, government seized DMAA-containing products from Hi-Tech worth nearly $19 million

2018: Case briefed/pending before U.S. Court of Appeals for Eleventh Circuit
Permanent Injunction

2017: U.S. District Court enters permanent injunction against Colorado companies and their owner to prevent distribution of adulterated and misbranded dietary supplements

– Marketing products as drugs

– cGMP violations/failed to establish specs for identity, purity, strength and composition of finished products

– Deficient labels/misbranded products

Indictment of USPlabs LLC

November 2017: DOJ announces unsealing of 11-count indictment against USPlabs LLC, S.K. Laboratories Inc. and executives

Allegations:

• USPlabs engaged in conspiracy to import ingredients from China using false certificates of analysis and false labeling

• USPlabs lied to retailers/wholesalers that it used natural plant extracts; used synthethic stimulant made in Chinese chemical factory for use in Jack3d/OxyElite Pro (OEP)

• Company broke promise to FDA to stop distribution of OEP following liver injuries outbreak

Indictment of Hi-Tech Pharmaceuticals Inc.

October 2017: News breaks of criminal indictment against Hi-Tech, its owner, Jared Wheat, and Hi-Tech executive, John Brandon Schopp

Superseding indictment:

• 18 criminal counts (conspiracy to commit wire fraud, wire fraud, conspiracy to manufacture and distribute controlled substances, manufacturing and distributing controlled substances, introducing misbranded drugs into interstate commerce)

• Indictment does not mention DMAA … but Wheat agreed to stop selling products containing it as condition of his pre-trial release from custody
Closing Remarks

Burden is on FDA to show supplements are adulterated, leading to potential long delays in removing products from the market and holding individuals/companies responsible.

But the dietary supplement industry **IS** subject to myriad regulatory requirements; and

There are **REAL** and **SERIOUS** consequences—both civil and criminal—for violating the Federal Food, Drug & Cosmetic Act (FDCA)

- Executives of companies can be held criminally liable for misdemeanor violations of FDCA without criminal intent (mens rea, i.e. “guilty mind”) so long as person is in position of authority to correct/prevent violation.
The ‘Wild West’

Is the dietary supplement market “a dangerous Wild West of inadequate regulation?”
Thank you

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