



Dietary Supplement Regulation: Recognizing Fact From Fiction

Wednesday, January 20, 2021

1



Handouts for today's presentations can be found at:

www.nabp.pharmacy/webinar

2



Financial Disclosures

We declare that neither we, nor any immediate family members, have a current affiliation or financial arrangement with any potential sponsor and/or organization that may have a direct interest in the subject matter of this continuing pharmacy education program within the last 12 months.

We do declare that we are NABP employees.

3



Presenters



Justin Macy, PharmD, JD
NABP Digital Health
Senior Manager



Niamh Lewis, JD
NABP Digital Health
Regulatory Expert

4



Why are we here?

5



- **More than two-thirds of Americans use supplements**
70% of Americans use dietary supplements
- **Significant number of adverse events**
Each year, 23,000 emergency department visits and 2,000 hospitalizations are attributed to adverse events related to dietary supplements.
- **Pharmacists can play an important role**
Pharmacists are the most accessible members of a patient's health care team.

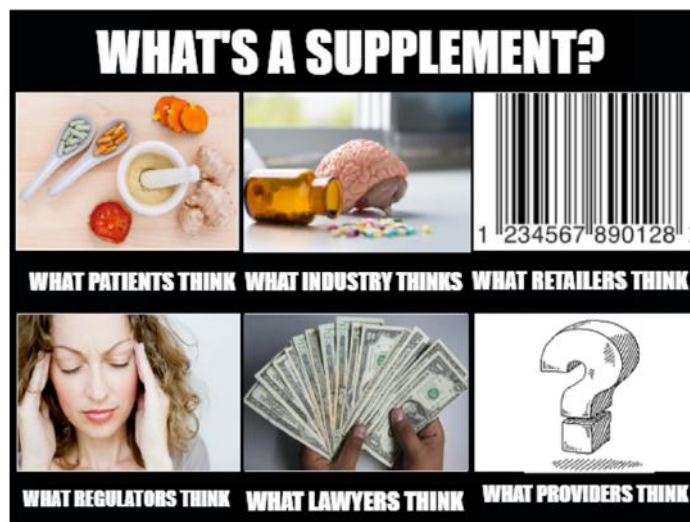


6



What is a dietary supplement?

7



8



**But what's the
legal definition?**

**First, we need to
define a drug.**

Drug Definition
21 U.S. Code § 321(g)

The term "drug" means

- (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and
- (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and
- (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and
- (D) articles intended for use as a component of any article specified in clause (A), (B), or (C) . . .

9



“

A food or **dietary supplement** for which a claim, [that is either approved or qualified,] is made in accordance [with other requirements of the law] is not a drug solely because the label or the labeling contains such a claim.

- Drug definition continued

”

A supplement is a legal exception to the definition of a drug.

10



The term “dietary supplement” —

- (1) means a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients:
- (A) a vitamin;
 - (B) a mineral;
 - (C) an herb or other botanical;
 - (D) an amino acid;
 - (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or
 - (F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E);

AND . . .

**So, what
exactly is a
dietary
supplement?**

11



The term “dietary supplement”—

- (2) means a product that—
- (A)(i) is intended for ingestion [...]; or
 - (ii) complies with [other laws];
 - (B) is not represented for use as a conventional food or as a sole item of a meal or the diet; and
 - (C) is **labeled as a dietary supplement**; and

AND . . .

**So, what
exactly is a
dietary
supplement?**

12



The term “dietary supplement”—

- (3) Does [not include an active pharmaceutical ingredient, unless it does].

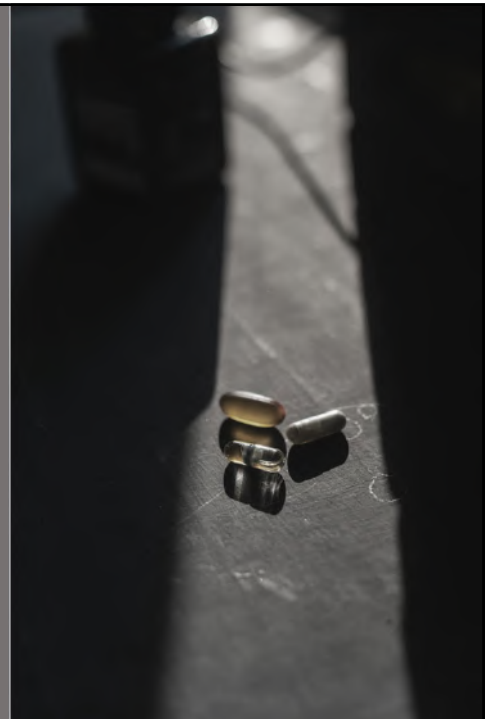
**So, what
exactly is a
dietary
supplement?**

13



Supplement Definition: Key Takeaways

- It's something that previously existed in the “diet of man” (unless it didn't).
- It's labeled as a supplement.
- It doesn't contain drug ingredients (unless it can).
- It doesn't make drug claims (unless it can).



14



How are dietary supplements regulated?

15



Dietary Supplement Health and Education Act of 1994 (DSHEA)

- Amended Federal Food, Drug, and Cosmetic Act
- Carved out exception in definition of “drug” for “dietary supplements”
- DSHEA, as written, was a **significant compromise** between regulators and supplement industry
- In response to DSHEA, the US dietary supplement market has grown from a **\$4 billion industry** comprised of about **4,000 products** to a **\$40 billion industry with at least 50,000 products.**

16



DSHEA: Marketing Requirements

Dietary supplements CAN be marketed with:	Dietary supplements CANNOT be marketed with:
<ul style="list-style-type: none">– “Approved” claims– “Qualified” claims– Nutritional deficiency claims (eg, scurvy, rickets)– General well-being claims– Claims to affect the structure or function of the body*	<ul style="list-style-type: none">– Explicit or implied disease claims, unless they meet an exception– Unsubstantiated claims to affect the structure or function of the body

* IF: (1) claims are adequately substantiated with competent and reliable scientific evidence; (2) Food and Drug Administration (FDA) is notified of the claims; and (3) the marketer posts the required disclaimer.

17



Approved Health Claim

Adequate calcium throughout life, as part of a well-balanced diet, may reduce the risk of osteoporosis.

--

Healthful diets with adequate folate may reduce a woman's risk of having a child with a brain or spinal cord birth defect.

DSHEA: Marketing Requirements Examples

18



Qualified Health Claim

Green tea may reduce the risk of breast or prostate cancer, although FDA has concluded that there is very little scientific evidence for this claim.

--

Four studies did not show that tomato intake reduces the risk of gastric cancer, but three studies suggest that tomato intake may reduce this risk. Based on these studies, FDA concludes that it is unlikely that tomatoes reduce the risk of gastric cancer.

DSHEA: Marketing Requirements Examples

19



Nutritional Deficiency Claim

Vitamin C treats scurvy. Scurvy is a disease that most commonly occurs in pirates from the 1700s. X% of the population are expected to suffer from scurvy.

DSHEA: Marketing Requirements Examples

20



General Well-being Claim

[Product] supports the proper functioning of a healthy immune system.

DSHEA: Marketing Requirements Examples

21



Structure Function Claims

Calcium builds strong bones
--
Maintains cholesterol levels that are already in the normal range
--
Fiber maintains bowel regularity

DSHEA: Marketing Requirements Examples

22



DSHEA: Ingredient Requirements

- Manufacturers and distributors that wish to market a dietary supplement that contains a "new dietary ingredient" must notify FDA about the ingredient.
- A "new dietary ingredient" is a "dietary ingredient" that was not marketed in the US before October 15, 1994, when DHSEA was enacted. There is no list of pre-DSHEA dietary ingredients.
- Dietary supplements may not include substances under investigation once substantial clinical investigations have been made public, unless the substance was found in the diet before it was authorized for investigation.

23



DSHEA: Misbranding

- A dietary supplement is *misbranded* if its "**labeling is false or misleading in any particular.**"
- **Labeling** is very broadly defined. It includes:
 - the manufacturer's or distributor's website, social media, customer testimonials, affiliate marketing, website's meta tags.
- A product is *misbranded* if:
 - the product label lists an ingredient that does not meet the statutory definition of a "dietary ingredient;" or
 - it is impermissibly marketed with claims to diagnose, mitigate, treat, cure, or prevent disease.

24



DSHEA: Adulteration

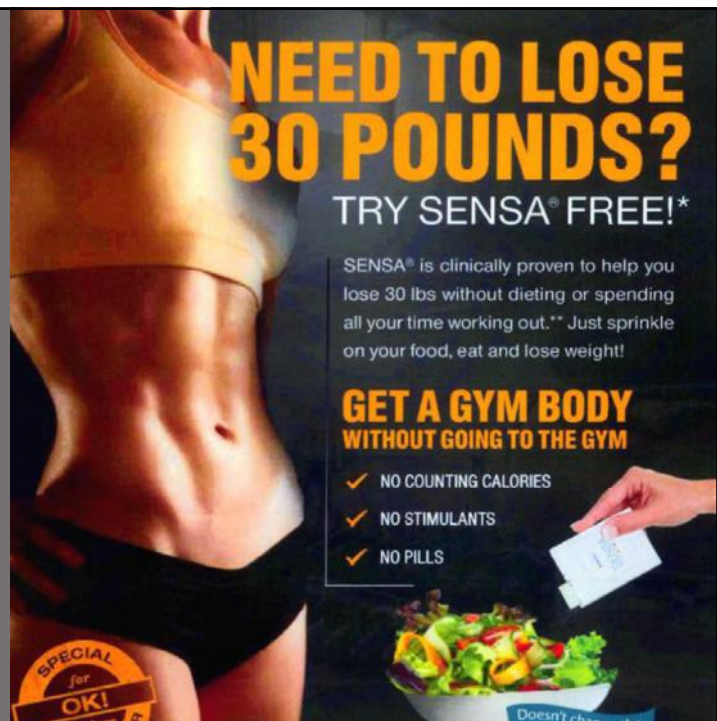
- A dietary supplement is **adulterated** if it “bears or contains any poisonous or deleterious substance which may render it injurious to health.”
- A product is **adulterated** if:
 - it contains a New Dietary Ingredient (NDI) that has not been noticed to FDA; or
 - the manufacturer or distributor has not submitted adequate evidence that a supplement’s NDI is “reasonably expected to be safe.”
- Examples of common adulterants:
 - PDE-5 inhibitors, designer steroids, CBD, stimulants

25



Federal Trade Commission

- **Truth-in-Advertising**
 - Advertising must be truthful and not misleading; and
 - Before disseminating an ad, advertisers must have adequate substantiation for all objective product claims.
- **Substantiation standard**
 - When evaluating claims about the efficacy and safety of foods, dietary supplements, and drugs, the FTC has typically applied a substantiation standard of competent and reliable scientific evidence.



26



When are dietary supplements problematic?

27



When are dietary
supplements problematic?

Bad claims
ingredients



28



Types of bad claims

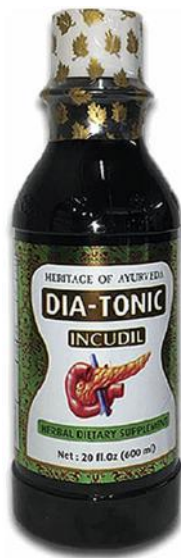
29



Disease claims

- Dietary supplements **cannot** be marketed with claims to diagnose, mitigate, treat, cure, or prevent disease.*
- May be expressed or implied

*Other than a classical nutrient deficiency disease or a few claims that have been authorized by FDA




"Provides health benefits such as:

- ✓ Helps in blood sugar control
- ✓ Helps to protect the nerves system
- ✓ It is helpful in weight management
- ✓ Helps to inhibit the formation of skin cancer. Displays anti-tumor effects on breast, lung, nose and throat cancer
- ✓ Helps to manage the imbalances and normalize the human body
- ✓ Helps liver to recover from alcohol and drug damage
- ✓ It is a natural remedy to protect from allergies


* This statement [sic] has not been evaluated by the Food & Drug Administration. This product is not intended to diagnose, treat cure or prevent any disease."

30


**NABP**
National Association of
Boards of Pharmacy

Unsubstantiated structure/function claims

- Claims must be truthful and not misleading
- FDA's and FTC's standards match: "competent and reliable scientific evidence"




31

**NABP**
National Association of
Boards of Pharmacy

Enforcement



- **FDA**
Warning letters, investigations, arrests
- **FTC**
Warning letters, injunctive relief, restitution, and consumer refunds
- **Department of Justice (DOJ)**
Complaints (often in conjunction with FDA)

**ABOUT THE FTC** | **NEWS & EVENTS** | **ENFORCEMENT** | **POLICY**

[Home](#) » [News & Events](#) » [Press Releases](#) » **FTC Approves Final Orders Banning Marketer Behind 'Fat Burner' Diet Pills**

FTC Approves Final Orders Banning Marketer Behind 'Fat Burner' Diet Pills From Making or Selling Weight-Loss Products

October 24, 2014

SHARE THIS PAGE  

FOR YOUR INFORMATION

TAGS: [Bureau of Consumer Protection](#) | [Consumer Protection](#) | [Advertising and Marketing](#) | [Health Claims](#)

Following a public comment period, the Federal Trade Commission has approved two final orders settling charges that the former CEO and co-founder of an Atlanta-based marketing operation and his company deceived consumers with promises that their Healthe Trim supplements would burn fat, increase metabolism, and suppress appetite.

According to the FTC's complaint, announced last month, John Matthew Dwyer III and HealthyLife Sciences, LLC made false and unsubstantiated claims that Healthe Trim supplements would cause rapid and substantial weight loss. Advertisements for Healthe Trim, which used the tagline "Get High School Skinny," relied heavily on consumer testimonials that portrayed losing weight as easy.

In settling the FTC's charges, Dwyer has agreed to be banned from the weight-loss industry, and is prohibited from manufacturing or marketing weight-loss products. HealthyLife Sciences is banned from making any of the severe weight-loss claims that the FTC has publicly advised are scientifically infeasible, with respect to any supplement over-the-counter drug, or any product rubbed into or worn on the skin. The settlement with HealthyLife Sciences requires that the company have two randomized, double-blind, placebo-controlled human clinical trials to support other claims relating to weight loss, increased metabolism, or appetite suppression.

The Commission vote approving the final consent orders was 5-0. (FTC File No. 122-3287; the staff contact is [Elizabeth A. ...](#))

32



Quiz Time!

Allowed or Prohibited?

“

This product has anti-inflammatory and antihistamine properties.

”

33



Quiz Time!

Allowed or Prohibited?

“

Q: What are the potential medical benefits of CBD?

A: Anti-convulsant suppresses seizure activity.

”

34



Quiz Time!

Allowed or Prohibited?

“

This herbal analgesic has been formulated to assist with aches, pains, and inflammation. It may produce a calming sedative effect while decreasing the body's perception of intense pain. Often used as an effective herbal alternative to over-the-counter pain relievers.

”

35



Quiz Time!

Allowed or Prohibited?

“

Product Name: Intestine Relaxer II (for Crohns)

”

36



Quiz Time!

Allowed or Prohibited?

“

Support for a woman's changing body during menopause.

”

37



Bad Ingredients

38



Sexual enhancement and weight loss supplements

- Sexual enhancement supplements may be tainted with sildenafil, tadalafil, and/or their analogues.
- Weight loss supplements may be tainted with sibutramine, a Schedule IV controlled substance. Others contain phenolphthalein or orlistat.



39



Bodybuilding supplements

Some bodybuilding supplements are **labeled** as containing ingredients that do not qualify as “dietary ingredients.”

Examples: SARMs, designer steroids, and stimulants such as DMAA, DMBA, DMHA, BMPEA



40



Cognitive enhancers

Also known as “nootropics,” some cognitive enhancement supplements are labeled as containing foreign drugs or investigational new drugs.

Examples: Picamilon and phenibut, which are approved drugs in the Russian Federation, and piracetam, which is an investigational new drug in the US.



41



Enforcement

- **FDA**
Warning letters, investigations, arrests
- **DOJ**
Complaints (often in conjunction with FDA)
- **State Attorneys General**
Oregon led the charge against major retailers that sold dietary supplements containing picamilon and BMPEA



Oregon Files Lawsuit Against GNC for Selling Nutritional Supplements with Ingredients Not Approved in U.S.

October 22, 2015 • Posted in Media Release

Attorney General Ellen Rosenblum today filed a lawsuit against General Nutrition Corporation, GNC, for selling nutritional and dietary supplements containing the illegal ingredients picamilon and BMPEA. The lawsuit alleges that the company violated the Oregon Unlawful Trade Practices Act (UTPA) by misrepresenting certain products as lawful dietary supplements when they are actually unapproved drugs that may not be lawfully sold in the United States as a dietary supplement. The complaint also alleges that GNC sold products labeled as containing botanical acacia rigidula that had been spiked with unlabeled BMPEA.

"It is scary to know that certain products sold by GNC contain an ingredient that is not even labeled—let alone approved in the United States," said Attorney General Rosenblum. "When Oregonians buy a dietary supplement, they deserve to know that the ingredients in the products are safe and comply with the law. There are 25 GNC stores in Oregon that sold thousands of these products over the span of a couple of years."

The lawsuit, which was filed in Multnomah Circuit Court, also alleges that GNC sold thousands of units of products in Oregon that contained picamilon or BMPEA that were falsely labeled as a dietary supplement.

Picamilon is a synthetic chemical that is not approved in the United States, but is used as a prescription drug in some countries to treat neurological conditions. Products containing BMPEA, a powerful stimulant and amphetamine-like substance, are sometimes sold as weight loss or performance enhancing nutritional supplements.

42



Clinical Pearls

43




Takeaways for counseling patients

- Supplements are not tested for safety prior to coming to market.
- Supplements are not necessarily “natural” or plant-based.
- Supplements are not without risks for patients.
- As suggested by their name, dietary supplements are intended to **supplement the diet**. With a few rare exceptions, they are not intended to treat diseases.
- The riskier categories include weight loss, sexual enhancement, and bodybuilding.



44



NABP
National Association of
Boards of Pharmacy

Report adverse events to FDA

- **Safety Reporting Portal**
<https://www.safetyreporting.hhs.gov/SRP2/en/Home.aspx>
- **FDA's MedWatch hotline number**
1-800-FDA-1088

Safety Reporting Portal

SAFETY REPORT DIRECTORY FAQs RELATED LINKS CONTACT

Begin Reporting Here

1. Login

EMAIL

PASSWORD

[Reset Password/Unlock Account or Reactivate Account](#)

☐ Remember me

Log In


2. Report As Guest

Not ready to create an account but would like to submit a report?

You can do that here.

Report as Guest

45




NABP
National Association of
Boards of Pharmacy

Submit Your CPE Claim

1. Claim your CPE credit by signing in to NABP's submission site:
<https://nabp.pharmacy/claimcpe> (case-sensitive)
2. Select the webinar from the Live Meetings and Conferences section
3. Enter the session code provided at the end of the webinar
4. Complete the course and speaker evaluations
5. Select the appropriate credit (pharmacist or pharmacy technician)
6. Enter your NABP e-Profile ID and date of birth and certify that the information is correct
7. Click the claim button

Claims for this live, knowledge-based activity must be submitted electronically by noon on March 15, 2021.



NABP® and NABP Foundation® are accredited by the Accreditation Council for Pharmacy Accreditation (ACPE) as providers of continuing pharmacy education (CPE). ACPE provider number: 0205.

Dietary Supplement Regulation: Recognizing Fact From Fiction
1 contact hour (0.1 CEU)
0205-0000-21-009-L03-P
0205-0000-21-009-L03-T

Questions about submitting your claim? Please contact Prof-Affairs@nabp.pharmacy prior to the deadline.

46