Supplements for Weight Management and Nutrition:

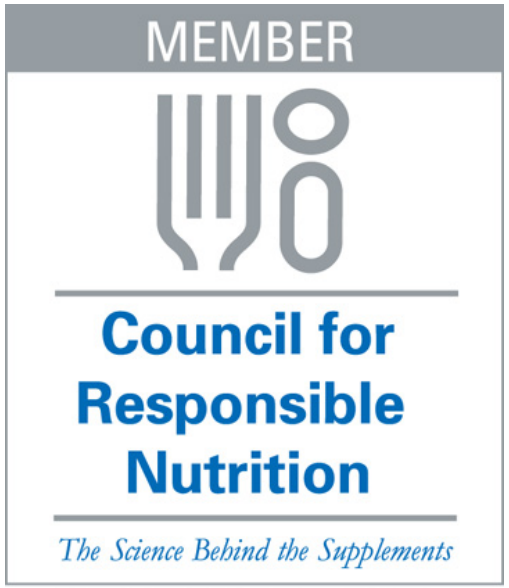
Helping Your Patient Navigate the Marketplace

Steve Mister, President & CEO
Council for Responsible Nutrition
November 1, 2016


Schiff
MegaRed
100% PURE OMEGA-3 KRILL OIL 300 mg


Garden of Life


Juice PLUS+


MEMBER
Council for Responsible Nutrition
The Science Behind the Supplements


BODY BUILDING.com


The Nutraceutical Company
nutRamax
LABORATORIES, INC.


Emergen-C


POM
WONDERFUL


THE Vitamin Shoppe
SINCE 1977
Answers For Every Body


Centrum


foodstate
nutritional intelligence


Country Life


vitafusion


DSM
BRIGHT SCIENCE. BRIGHTER LIVING.


NOW


EMBRIA
Health Sciences


NOW
Nutrition for Optimal Wellness™


EAS
SPORTS NUTRITION


Cargill


NATURE'S BOUNTY
Perfect For Every Body™


Nature Made
FUEL YOUR GREATNESS.SM


Abbott
A Promise for Life


SMARTY PANTS


FLINTSTONES™
COMPLETE


HERBALIFE.


ADM


ONE A DAY
Men's Health


BASF
The Chemical Company

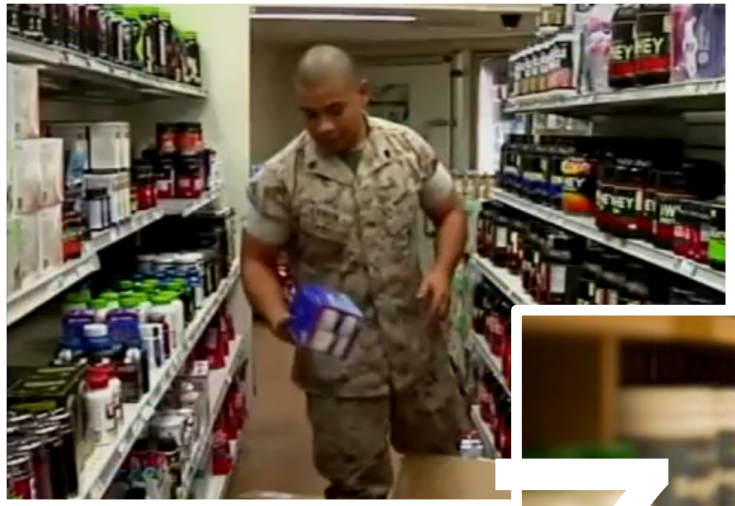

RENEW LIFE
The Digestive Care Company®


Shaklee


KEMIN
INSPIRED MOLECULAR SOLUTIONS™

Dietary Supplements Have a Role in Weight Management & Overall Nutrition

- **Influence on energy intake**
  - Bulk (fiber) agents / satiety
  - Appetite suppressants
  - Slow carbohydrate or fat absorption
- **Influence on energy expenditure (thermogenic)**
  - Metabolism enhancers
  - Fat burning mediators
- **Mediate health conditions associated with obesity**
  - Glucose control
  - Blood pressure
  - Triglycerides
  - Cholesterol
- **Address nutrient deficiencies**
  - Vitamins, minerals, nonessential nutrients

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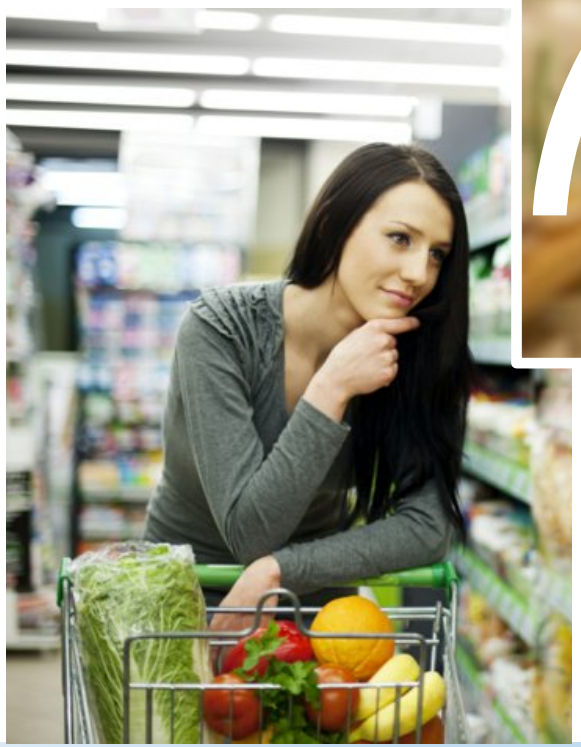


What the media says…

"These views are often fueled by product health claims, consumer testimonials, and an industry that is largely unregulated owing to the 1994 Dietary Supplement and Health Education Act." *Archives of Internal Medicine*

"The sentencing ends an unusual criminal case that explored both illegal online pharmacies and the legal but barely regulated U.S. dietary supplements industry." MSNBC

"An unregulated industry" *Consumer Reports*

"The consumer should understand that the dietary supplement market is mostly unsupervised and unregulated…" *The Legal Examiner*

"Dietary supplements are not strongly regulated or evaluated for claims by the FDA …" *NewsStar.com*

"So why aren't these products regulated? Congress virtually exempted them from oversight under a 1994 law…" *Concord Monitor*

"Fifteen years after Congress and the Clinton administration put the dietary-supplement industry on a loose leash, the $25-billion-a-year business still sometimes bites its customers… The dietary-supplement industry is essentially unregulated," *Philadelphia Inquirer*

". . . these products are both widely used and largely unregulated by the U.S. Food and Drug Administration." *NewsDay*

"…supplements are not regulated…" *Nutrition-wise Blog, Mayoclinic.com*

But in fact,

- **Dietary supplements are extensively regulated by FDA**
  e.g., GMP regulations, Adverse Event Reporting, "Supplement Facts" labeling, claims requirements, NDI notifications, FSMA registration, etc.

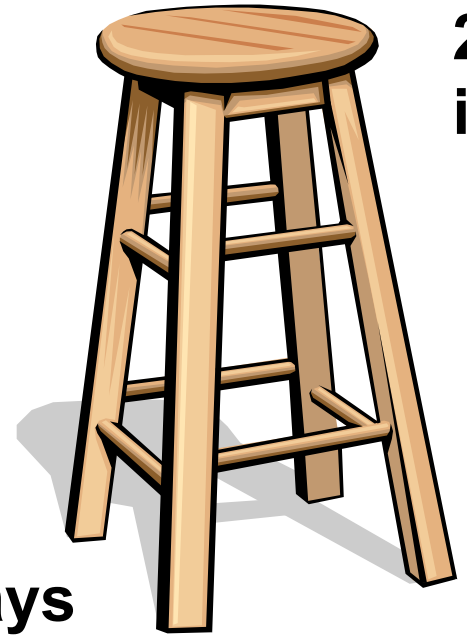
- **Advertising claims are regulated by the FTC**
  All advertising must be "truthful, not misleading and substantiated with credible and reliable scientific evidence."

- **FDA and FTC have a variety of enforcement tools available to compel compliance**
  (seizures, recalls, detentions, injunctions, civil & criminal actions)

Regulation is a Four-Legged Stool

Ingredient Safety

1. The ingredients are safe.



Manufacturing Controls

2. The product is manufactured in a manner that assures quality.

Claims Evaluation

3. The ingredients are effective; i.e., the product does what the marketer says it will do.

Post-Market Surveillance

4. Someone is monitoring the product in the marketplace.

Ingredient Safety

- If a dietary ingredient was on the market in 1994, when DSHEA was enacted, it is presumed to be safe unless the FDA demonstrates that it is not. ("grandfathered ingredients")
- After twenty-two years, we have additional usage data to further support the safety of these old ingredients, along with mandatory adverse event reporting since 2008.
- New dietary ingredients (introduced since 1994) must be "noticed" to FDA at least 75 days before entering the market.
- Manufacturers must describe the ingredient with specificity and provide FDA with evidence that the ingredient, and product that would contain it, are "reasonably expected to be safe."
- Failure to notify FDA of a new ingredient is *per se* adulteration; product can be seized, recalled, prosecuted.
- **FDA can remove ingredients or products from the market if they pose a significant or unreasonable risk of illness or injury – and it has used that authority.**

Manufacturing Controls

- Manufacturers must register their facilities with FDA every two years.
- Dietary supplements are subject to their own Good Manufacturing Practices (GMPs) regulations, effective for industry since 2010. (21 CFR Part 111)
- GMPs govern all aspects of dietary supplement production, from identity testing of raw ingredients to testing of the final products.
- FDA routinely inspects dietary supplement facilities, completing nearly 500 inspections a year in 2013, 2014 and 2015.
- Warning letters for uncorrected violations are routinely issued and posted on FDA's website.
- Failure to comply with GMPs makes the supplement *per se* adulterated and subject to seizure, recall and criminal or civil penalties.

Claims Substantiation

- **Disease claims** are prohibited – Dietary supplements may not claim to treat, cure, prevent or mitigate a disease.
- Structure/function claims – Marketers must inform FDA of the claim within 30 days of making it.
- Health claims (i.e., claims that a supplement can reduce the risk or incidence of a disease) must be approved by FDA; can be qualified.
- Even nutrient content claims (*"a good source of vitamin C"*) are subject to FDA restrictions.
- Marketers must have data to substantiate *any* claims they make.
- FTC reviews advertising claims and brings actions for false, misleading and unsubstantiated advertising.

Post-Market Surveillance

- 2006 law imposed mandatory adverse event reporting – with support of the industry. It's the same requirement as OTC medicines.
- All serious adverse events reported to a company must be reported to FDA within 14 days of receipt. No determination of causality: all reports go to FDA.
- Companies must preserve all adverse event reports for six years; FDA has access upon request.
- These adverse event reports have proven helpful to identify manufacturing problems, safety concerns for ingredients and discrepancies in labeling.

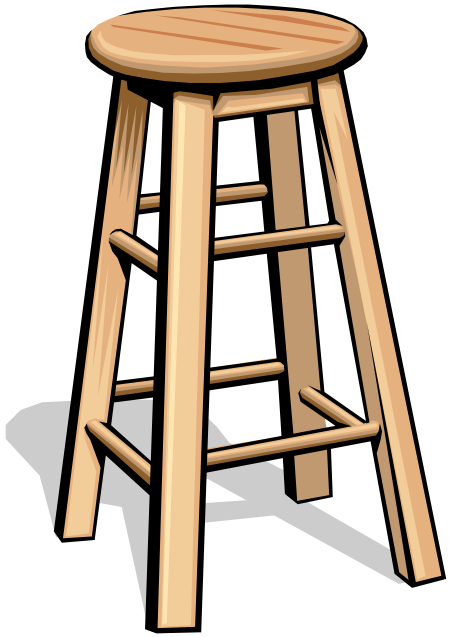
So the reality is….
Dietary Supplements *ARE* Regulated!

Ingredient Safety

1. The ingredients are safe.

Claims Evaluation

3. The ingredients are effective; i.e., the product does what the marketer says it will do.



Manufacturing Controls

2. The product is manufactured in a manner that assures quality.

Post-Market Surveillance

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So how did we get from this . . . to this?

The Regulatory Reality

- The Dietary Supplement Health & Education Act regulates dietary supplements *differently* than either drugs or conventional food, but rather somewhere in between.
- DSHEA provides FDA with a variety of tools for enforcement, but FDA has not effectively used the tools it has been provided.
- The industry has grown much faster that FDA's ability to keep up.
- FDA is hampered by too many priorities and insufficient resources, staffing and funding—and sometimes lacks the political will to act.
- But overall, supplements enjoy a wide margin of safety compared to other products that FDA regulates.

So how do you guide your patients?

Ingredient Safety

- Know what's in the products you recommend—and why it's there.
  - Do your research; review the studies; check online resources.
  - Ingredients: Is it old or is it new?
  - Beware of "proprietary blends."
- Look for reputable brands—particularly online.
- Coming soon: The Supplement **OWL** (**O**nline **W**ellness **L**ibrary)

SUPPLEMENT **OWL**
ONLINE WELLNESS LIBRARY

SUPPLEMENT **OWL**

Nutrient | Help

Enter Search Keywords

Home > Nutritional Products > Women's Multivitamin Gummies

Women's Multivitamin Gummies

ID: DS1888687

Company: Nature's Bounty

Tags:

Nature's Bounty® Op
women — to provide
gummy.* Nature's Bo
support a healthy and
for bone health and V
convert food into ene

Share

Documents

General Information

Label (English) Google Translate

Certification Statement

CGMP Certification - TEST (English) Goog

Contact Information	NATURE'S BOUNTY, INC. Bohemia, NY 11716 U.S.A. 1-800-433-2990
Manufacturing Facility Contact	NATURE'S BOUNTY, INC. Bohemia, NY 11716 U.S.A.

Dietary Ingredients Per Serving

1 Servings Calculate Reset

Amount Per Serving	% Daily Value
Calories 15	
Total Carbohydrate 3000mg	1%
Sugars 2g	
Vitamin A (as Retinyl Acetate) 2500IU	50%
Vitamin C (as Ascorbic Acid) 30mg	50%
Vitamin D (as Cholecalciferol D-3) 1000IU	250%
Vitamin E (as Dl-alpha Tocopheryl Acetate) 30IU	100%
Vitamin B-6 (as Pyridoxine Hydrochloride) 2000mcg	100%
Vitamin B-12 (as Cyanocobalamin) 9mcg	150%
Biotin 600mcg	200%
Calcium (as Dicalcium Phosphate) 100mg	10%
Iodine (as Potassium Iodide) 40mcg	27%
Zinc (as Zinc Citrate) 2.5mg	17%
Collagen 50mg	

Supplement Details

Product Information | Nutritional Product Facts | Label Statements | Contact Information | Dietary Ingredients Per Serving

Product Information

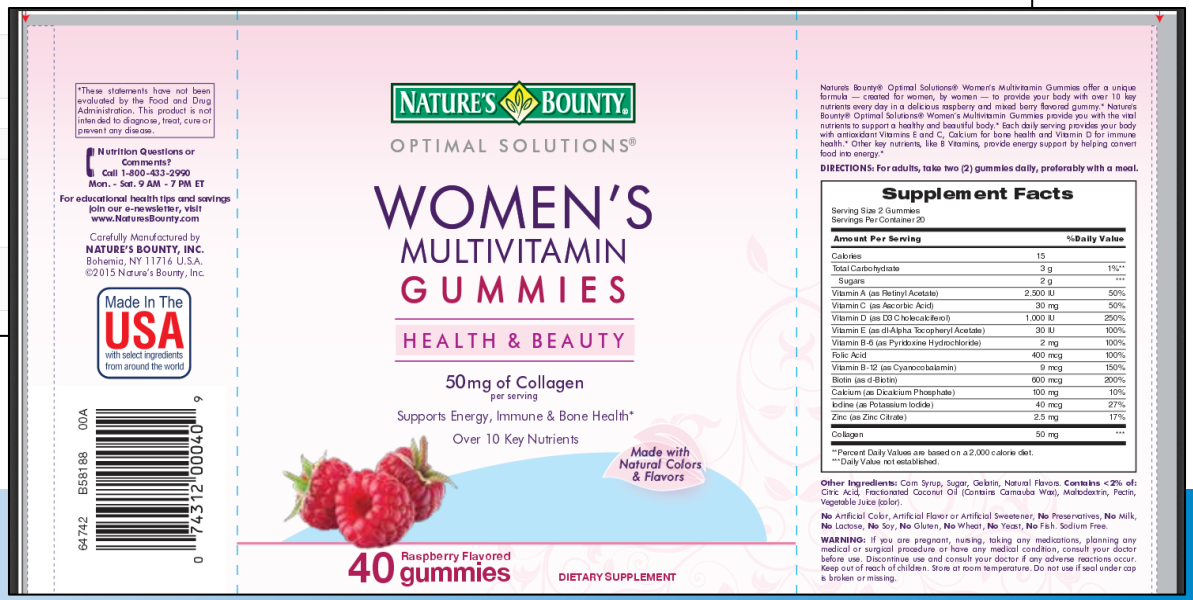
Delivery Form	Gummy
Intended User(s)	Adult, female
Label Type	Supplement Facts
Product Category	Women's Health
Statement of Identity	DIETARY SUPPLEMENT

Nutritional Product Facts

Other Ingredients
Serving Directions
Serving Size
Servings Per Container

Label Statements

Allergen Statements / "No" Claims
FDA Disclaimer Statement



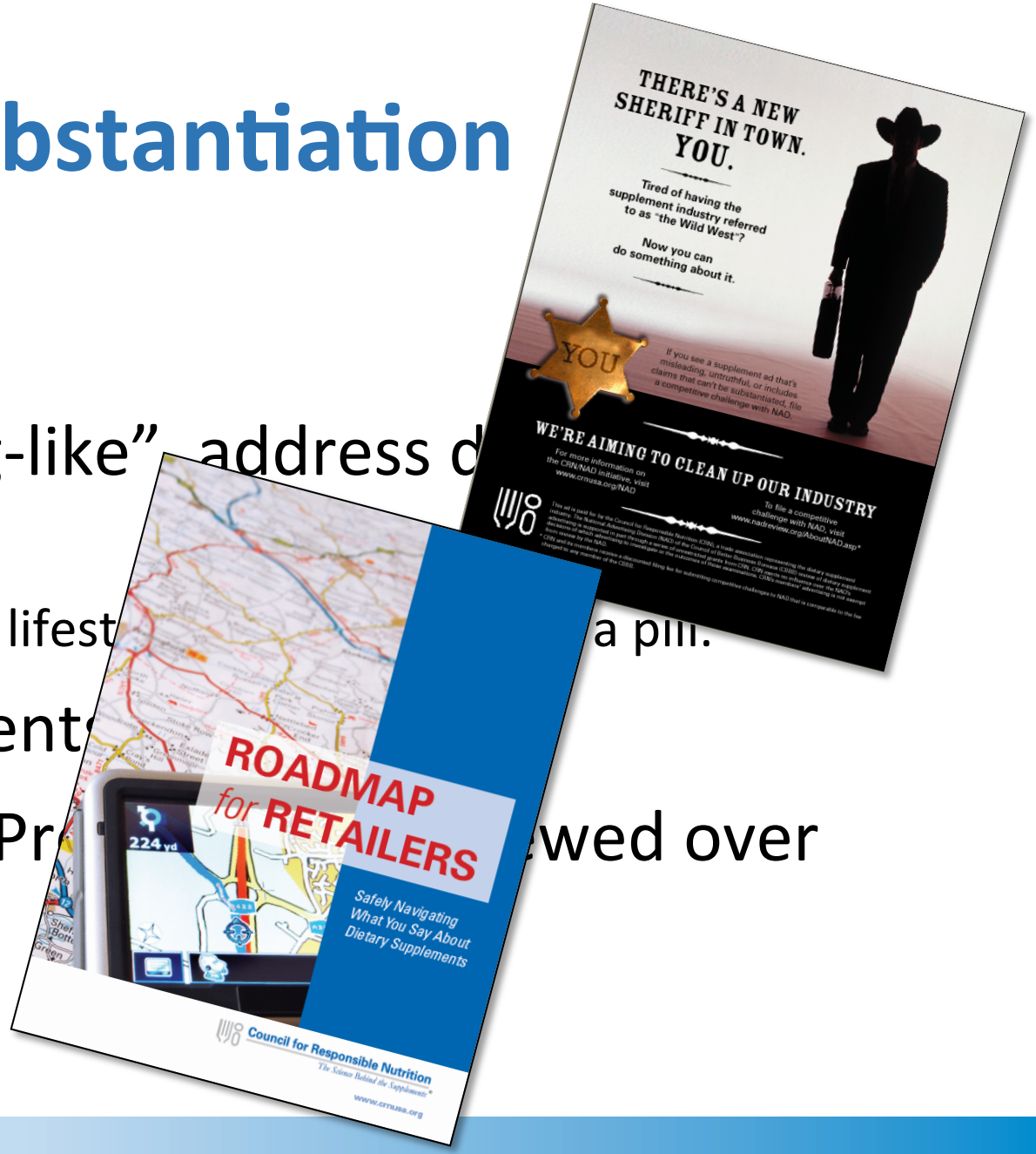
SUPPLEMENT **OWL**
ONLINE WELLNESS LIBRARY

Council for Responsible Nutrition

Manufacturing Controls

- Look for third party certifications from reputable organizations.
  - E.g., USP Verified, NSF Certified for Sport, UL, Informed Choice
- Look for reputable brands—particularly online.
- You can search FDA's warning letters at CRN's website. www.crnusa.org/warningletters

Claims Substantiation



- There are no magic bullets!!
- Avoid claims that sound "drug-like", address d… sound too good to be true.
  - Particularly for weight-loss: involves lifest… a pill.
- Check the amounts of ingredient…
- CRN-NAD Advertising Review Pr… wed over 270 ads.
- CRN's *Roadmap for Retailers*

Post-Market Surveillance

- Ask your patients what supplements they are taking.
- Be aware of potential drug-supplement interactions and potential nutrient depletions that can be offset with supplements.
- Report suspected adverse events to FDA.

  (MedWatch: http://www.fda.gov/Safety/MedWatch/)

- Review adverse event data if you have a concern—but be careful: AER data should be interpreted and understood in context.

HEALTHY HABITS

DIETARY SUPPLEMENT CONSUMERS ARE MORE LIKELY TO ENGAGE IN OTHER HEALTHY HABITS THAN PEOPLE WHO DO NOT TAKE SUPPLEMENTS.

www.crnusa.org/CRNconsumersurvey/2015/

OPEN A DIALOGUE

SUPPLEMENT USERS TALK WITH THEIR DOCTOR ABOUT THE SUPPLEMENTS THEY TAKE –YOU SHOULD, TOO!

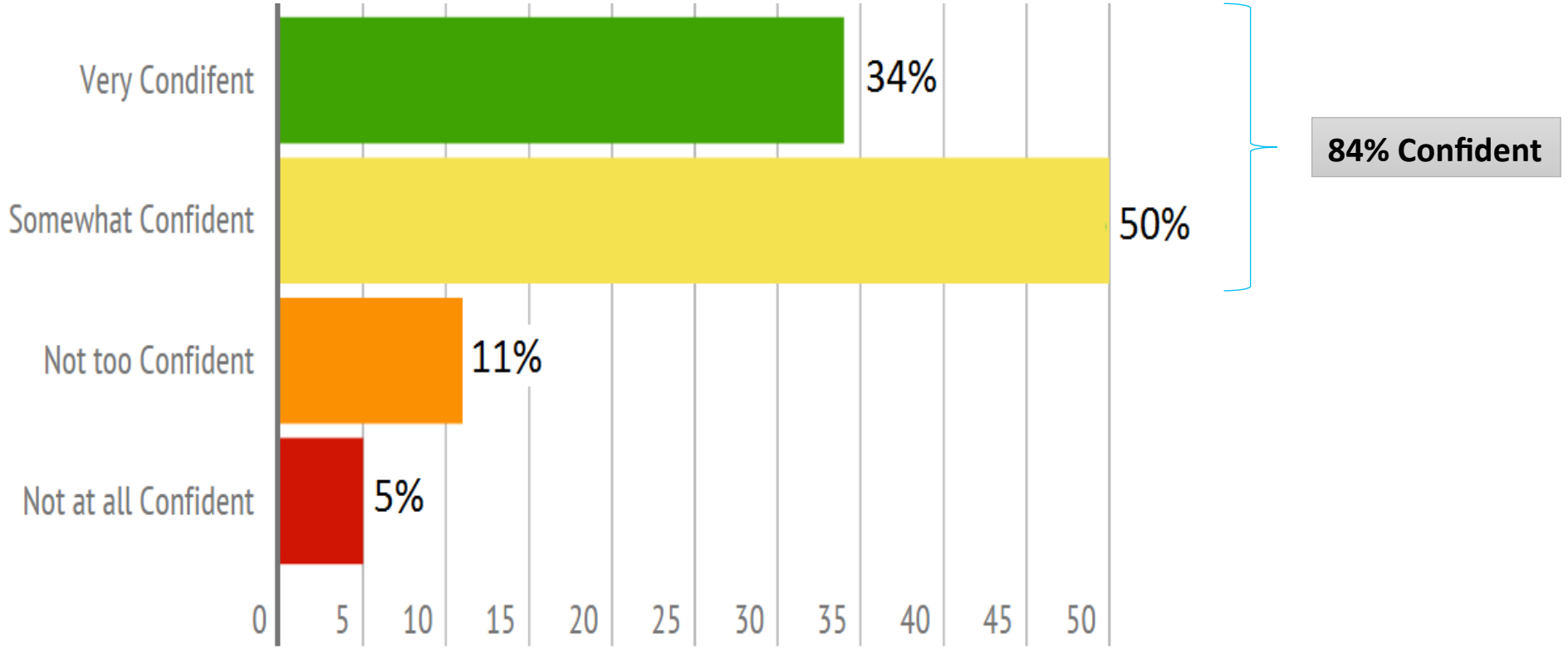
Nurse practitioners, pharmacists, registered dietitians and other health care practitioners are also good resources for dietary supplement information.

www.crnusa.org/CRNconsumersurvey/2015/

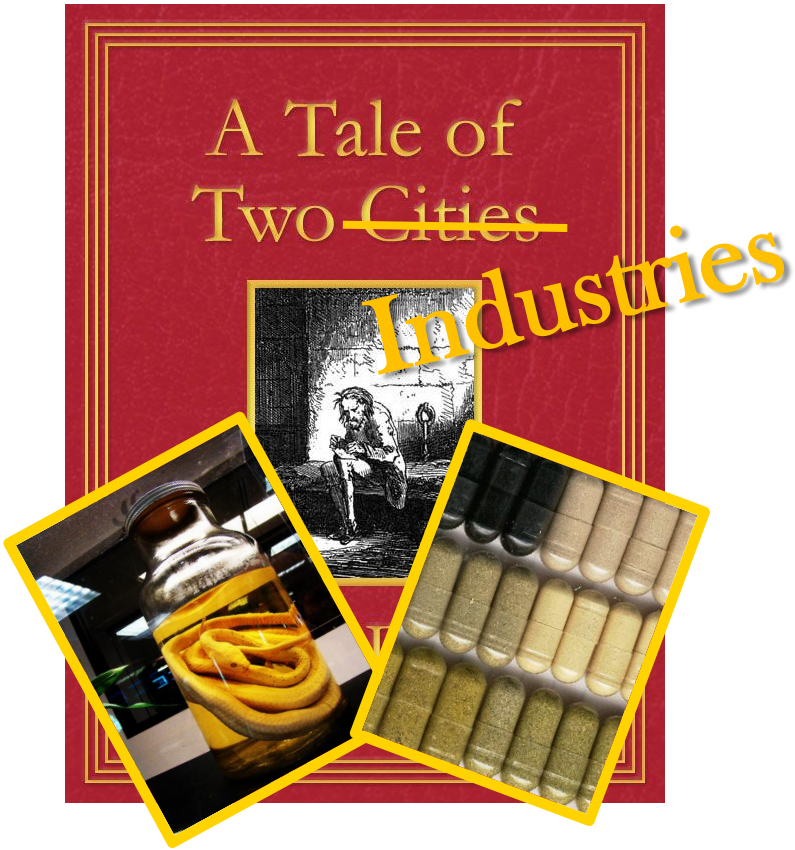
In 2015…

84% of U.S. Adults Report Being Confident in Supplements

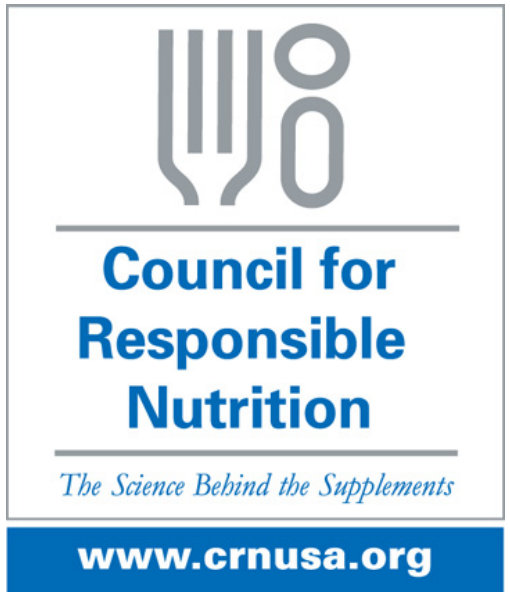
A Third of U.S. Adults are “Very” Confident & Half are “Somewhat” Confident.



Q: “How would you describe your overall confidence in the safety, quality and effectiveness of nutritional or dietary supplements?” Base: US Adults (n=2,016)



We all have a role — industry, regulators, clinicians, researchers, consumer organizations and consumers themselves — to help consumers identify legitimate, quality products with proven benefits that improve health, and to help them steer clear of less reputable ones.



Thanks for listening!

For more information, see our website at www.crnusa.org