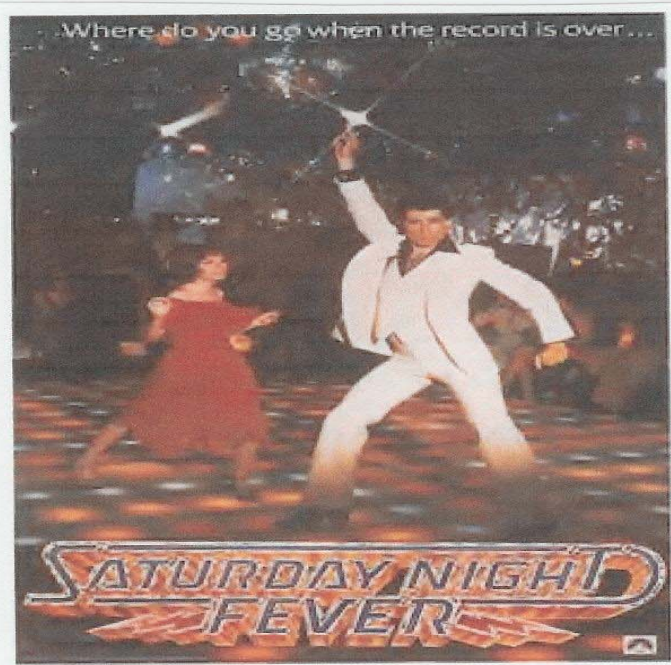


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Dietary Supplements 2016, or A Workable Path through the Dietary Supplement Jungle



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Our Objectives today

ID:

--2 concerning issues with DSHEA Act

**--Methods of verifying quality of suppl
in US**

Determine credibility of label/ads

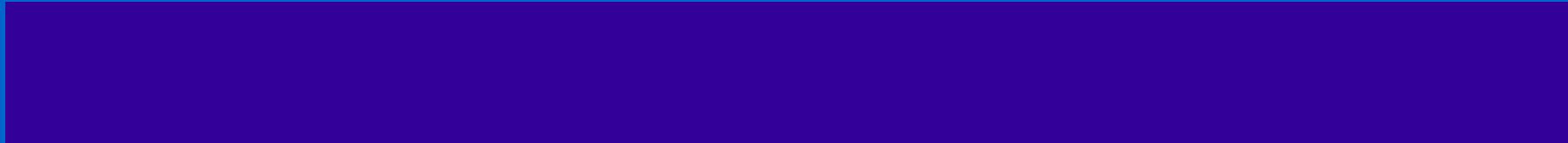
**Communicate more effectively with
patients about these products**

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First Case

- **3 nurses came to outpt pharmacy to buy products for Mrs U, soon to be sent home from hospital**
- **Resp illness >>> immune boost**
- **Chose Emergen-C**
- **Extra vit C in throat lozenge**
- **Recomm. plenty of o. j. at home**

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Institute of Medicine

- **Upper limit of Vit C/day 2000mg.**
- **Vit C—gi irritation, kidney stones**
 - Can take off tooth enamel, used in cosmetics to remove top layer of skin

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History of Supplement Explosion

Linus Pauling-70's >>>3000mg Vit C

-Neutraceutical mfr/lobby wanted to separate their products from requirements of prescription/OTCs

-Convinced Congress of innate safety, no risk as food ingredient

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DSHEA is born

- 1994-vitamins, minerals, herbs etc
- --NOT products with risks...not for prevention or treatment of disease
- --“far less stringent” regulations than drugs(research not required)
- --FDA has minor regulatory role
- --no pre-mkt approval, minimal cGMP
- --FTC regulates label

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Dietary Supps Today

- **These “Innocuous products”**
- **now \$40 billion market**
- **30,000-50,000 products in US**
- **Many are contaminated, adulterated, or counterfeit**
- **May not have factual labels**
- **Not easy to ID content, purpose, SE**

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Dietary Supps today

- **Side effects are often not recognized, reported, or predictable**
- **23,000 ED reports just last year**
 - Especially wt loss, energy, performance, sexual supps
 - Pharmaceuticals (sildenafil, sibutramine), illegal drugs, or very high amounts of caffeine and caffeine-like chemicals (taurine, ginseng, glucuronolactone, guarana, garcinia, etc)

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Energy/Performance Category

- **Contain stimulants and heighten metabolism>>> at a cost of SE**
- **So little info was collected with adv effects, that in 2007, addendum added forcing mfr rept serious SE**
- **Some Energy drinks>>> were dietary supps>>> now beverages**

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Beverage vs Dietary Supplements

- **Beverage category:**
- **Force mfr to report ingredients accurately on label**
- **Deaths /injuries ARE NOT REQUIRED to be reported**

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Dietary Suppl/Energy

- In 2011, more than 20,000 ED visits
- H/A, anxiety, rapid heart rate, irregular heart beat, seizures, coma, death
- No limit to amount of caffeine and caffeine-like ingredients in dietary supplements

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Energy/Performance Enhancers

- Taurine, guarana, garcinia, glucuronolactone, carnitine, ginkgo biloba, ginseng, milk thistle extract
- Significant SE, along with stimulation/wt loss (5 hr energy)
- Recent concern with GNC suppl containing BMPEA (amphet-like), picamilon (Rx/UK)-illegal drugs

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Sports-whey/soy protein shakes

- **2010 Consumer Reports investigated quality of ingredients**
- **Muscle Milk found to contain the largest amount of heavy metal content, including lead, mercury, cadmium and arsenic**
- **Muscle Milk popular and cool**

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Mainstream acceptance of suppl

- Many health systems offer dietary suppl both to patients and in phcy/cafes as part of total wellness
- 94% DR recomm vits/minerals to some
- 45% recomm herbals
- 7% sell suppl in offices (GALLUP)

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JAMA 10/11/16 Probiotics

- **Probiotics as treatment for antibiotic associated diarrhea in infants/children**
- **23 studies showed some benefit**
- **No specific formulation has been identified**
- **To study properly-one formulation should be submitted as NDA**
- **\$\$\$ research not usually from mfr**

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Recent case in Connecticut

- **Premature infant in ICU received probiotic (hosp protocol) to promote proper gut organisms (dietary supp brand chosen was deemed “safe”)**
- **Child acquired fungal infection linked to the product chosen**
- **Child died**

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Probiotic Case

- **Family and hospital now have legal battle ---child “poisoned”**
- **Probiotic was contaminated—Solgar**
- **ABC Dophilus Powder**
- **Recalled by FDA**
- **Use greater caution in using suppl containing live bacteria—**
- **AHSP:hard to make “safe” choices**

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Recent Diet Supp recalls:

Ton Shen, Life Rising -high levels lead

- **DHZC-2 tabs (for blood problems)**
- **Mfr-describing purpose for use as:
“too complicated to discuss”-2 died**
- **Side Head Regulator TT tabs-recalled
this week-children testing high in
lead exposure**

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Recent Dietary Supp recalls:

- **Skinny Bee Diet (mfr-Love my Tru Body)—undeclared drug ingredients**
- **Sibutramine, desmethyilsibutramine, and phenolphthalein**

(sibutramine w/d as drug 2010; phenylphthalein – genotoxic/laxative-pulled off mkt as drug 1999)

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www.fda.gov

- **72 similar wt loss recalls March 2016**
- **Tainted wt loss products, sexual enhancement products, sports supplements-recalled every week for hidden active ingredients that could be harmful**
- **Majority of Ayurvedic products in US tainted with heavy metals**

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Communicating with patients

Med reconciliation needs re-vamping---

In non-judgmental/consistent way:

- **Patients may not understand suppl**
- **“NOT like medicines/drugs”**
- **NATURAL=safe, no risk**
- **Ask “what other health-related products” they “take daily or once in awhile” and “is there anything else?”**

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Helping Patients Evaluate Supps

Prevention vs Treatment - supps not approved for either

SUPPL cannot replace RX drug!!!

- **Who or what is the source of recomb? Credibility? Testimonials?**
- **Benefits vs. Risks>>> all biologic substances have risks**
- **Familydoctor.org, medlinePlus**

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Labels/health claims

- **Gov't agencies lax on: "what is stated on the label" is accurate (ingred/claim)**
- **Falsely advertising a dietary suppl. as a cure or medical treatment is a crime**
- **FDA requires NDA and clinical studies to substantiate medical claims**

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Verifying Quality

- **US Pharmacopeia**
- **Dietary Suppl Verification Program (USP, DSVP) at <http://www.usp.org>**
- **Mfr voluntarily have product tested—USP verified--seal**
 - (150mg of X is just that—does not prove efficacy or safety)
- **Many mfrs try to fake this seal**

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Popularly Promoted

- Kava-Kava (stress reducer)**
- **St. John's Wort (for down days)**
- **Melatonin (to prevent jet lag)**
- **Joint Juice-glucosamine/chondroitin**
- **Fish Oil –now disproven for heart benefits-may be justified for high triglyceride levels, but it can increase LDL ---approp dose?**

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As H/C profs evaluate new info

- **Patients may not recognize that a new study has negative result, or has shown no difference between product /placebo, or that significant side effects exist**
- **Research often not paid for by mfr**
- **Chromium Beta-Carotene**

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Always Avoid

- **Aconite**
- **Caffeine Pwd**
- **Chapparral**
- **Comfrey**
- **Coltsfoot**
- **Germander**
- **Gr.Celandine**
- **Yohimbe**
- **Green Tea Extract Pwd**
- **Red yeast rice**
- **Lobelia**
- **Methylsynephrine**
- **Pennyroyal**
- **Usnic acid**
- **Kava kava**

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Case

- **Florida rheumatologist recommended “Limbrel”, a medical food, to patient (note—NOT Enbrel)**
- **She started the medical food- within weeks patient was dizzy, with dementia/ mm instab/gen'l fatigue**
- **Primary care doctor/NP saw her— began cholinesterase inhibitor**

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Limbrel (flavocoxid-proprietary)

- For clinical dietary management of the metabolic processes of OA
- SE: heaviness in legs, dizziness, red/scaling skin, liver toxicity
- Flavocoxid –Scutellaria baicalensis (skullcap), and Acacia catechu (catechin)-both assc liver injury

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Case Resolution-RPh involved

Medication Therapeutic Management
scheduled at patient's request for
concern of new symptoms—indep
RPh communicated with primary
physician/NP, rheumatologist and
patient to clarify the risks/SE—
Patient d/c'd Limbrel—with re-
evaluation for cholinest inhib.

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Where Do We Go From Here?

- **Help patients by using nonjudgmental techniques and motivational interviewing**
- **Talk with them about their use of all “other health-related” products**

Advise them on how to evaluate health info—and how to report adverse effects 1-800-FDA-1088

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How does one find accurate info?

- www.fda.gov -fact sheets available
- www.ods.od.nih.gov ofc dietary
suppl  pubmed subset
- www.nccih.nih.gov nat'l ctr compl
and integrative health
- Medline plus-consumers
- Medline--NIH NLM-pubmed for us

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Supplements of benefit-for some

Multi-vitamin

Vit D

Folic acid

Vit B12

Selenium in moderation

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Supps of Benefit for some

- **Macular degeneration-Vit C/E, copper, lutein, zeaxanthin**
- **What to do instead of adding unproven supps—eat nutritional diet and exercise**
- **Calcium containing foods: milk, sardines, leafy veggies, cheese, yogurt**

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Resources

- **Utilize R.Ph.-----medical librarian**
- **Seek out credible references (show patients how to do this)**
- **Share your concerns with patient and ask his/her opinion**
- **Help keep them informed of current conclusions on this topic**

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After dietary supp discussion:

- **Just once I would like to read a **FACTUAL** label that says:**
- **WARNING: may cause permanent weight loss, remove wrinkles, and increase energy.**
- **If it sounds too good to be true—it usually is.....**

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An Old Adage

- **Old pharmacists**
- **NEVER die,**
- **They just lose their potency**