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

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Where do you go when the record is over...
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
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
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
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
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 not required)
• --FDA has minor regulatory role
• --no pre-mkt approval, minimal cGMP
• --FTC regulates label
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
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)
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
Beverage vs Dietary Supplements

• Beverage category:

• Force mfr to report ingredients accurately on label

• Deaths /injuries ARE NOT REQUIRED to be reported
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
Energy/Performance Enhancers

- Taurine, guarana, garcinia, glucuronolactone, carnitine, gingko 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
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
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)
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
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
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
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
Recent Dietary Supp recalls:

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

(sibutramine w/d as drug 2010; phenolphthalein – genotoxic/laxative-pulled off mkt as drug 1999)
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
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?”
Helping Patients Evaluate Supps

Prevention vs Treatment - supps not approved for either
SUPPL cannot replace RX drug!!!

• Who or what is the source of recomm? Credibility? Testimonials?
• Benefits vs. Risks>>> all biologic substances have risks
• Familydoctor.org, medlinePlus
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
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
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?
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
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
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
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 assoc liver injury
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.
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
How does one find accurate info?

- [www.fda.gov](http://www.fda.gov) - fact sheets available
- [www.ods.od.nih.gov](http://www.ods.od.nih.gov) ofc dietary suppl → pubmed subset
- [www.nccih.nih.gov](http://www.nccih.nih.gov) nat’l ctr compl and integrative health
- Medline plus-consumers
- Medline--NIH NLM-pubmed for us
Supplements of benefit-for some

- Multi-vitamin
- Vit D
- Folic acid
- Vit B12
- Selenium in moderation
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
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
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.....
An Old Adage

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