

Case-Focus: Homeopathic Remedies vs Dietary Supps

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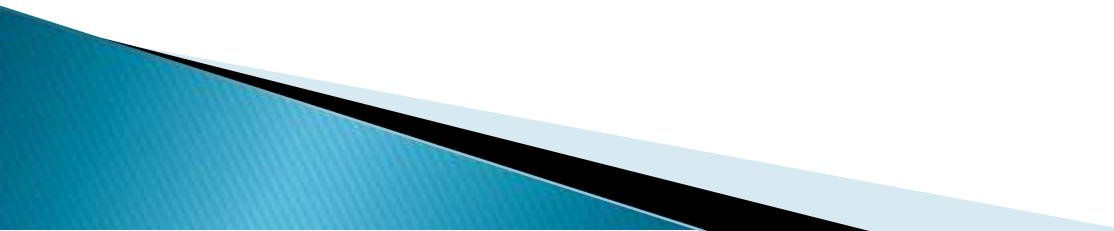
Dietary supplements and Homeopathy

Question 1: Myth or Fact:

“Even though a supplement or homeopathic prep may not help, at least it won’t hurt...”

H/C pros need to identify where a product falls on spectrum of “fact vs fiction” before having a conversation on it with a patient—part of professionalism.

Objectives

- ▶ ID homeopathic products vs dietary supps --
--and a bit about medical foods
 - ▶ Evaluate each for benefit vs risk, learn to search each product for available info
 - ▶ Assess recommendations, examples in wt loss, energy enhancement, and performance products
- 

Healthy Living



Zipfizz Healthy Energy Drink Mix, 30 Tubes
Lemon flavor, #100018700
Search*: ZIPFIZZ
\$29.99 Delivered



reViva Liquid Calcium or Liquid Multi
Valid 5/11/18-5/27/18
Search*: REVIVA18MCG
\$19.99 Delivered After \$4 OFF



NSF

Cosamin ASU for Joint Health, 230 Capsules
Valid 4/27/18-5/25/18 #007654
\$41.99 Delivered After \$8 OFF

trunature Lutein & Zeaxanthin or Grape Seed & Resveratrol
Valid 4/19/18-5/13/18
Search*: TRUNATURE
\$4 OFF Delivered



trunature Versicol Collagen Powder
2,500 mg, 10.62 Ounces
#1215667
\$19.99 Delivered

Natrol Fruit & Veggie or Melatonin Time Release 5 mg
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Search*: NATROL 15MCG
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NATROL

Irwin Naturals Brain Awake or Garcinia HCA Extract
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FOCUSfactor Kids, 150 Chewable Tablets
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USDA ORGANIC

Regulations: Dietary Supps

DSHEA Act-1994: treated as supplements to food/no risks/ingested

Not for prevention, treatment or cure

FDA-can act assertively if >100 are harmed-any health claims must be approved

FTC-regulates advertisement and labels


GMP-requirement

HARD TO MONITOR


Many poor quality products-false claims, counterfeit, and adulterated products

FDA Medwatch: 1-800-FDA-1088

Homeopathy

- ▶ “Let likes be cured by likes” Samuel Hahnemann—father of homeopathy—High dose— cause disease, low dose —cure: cinchona bark fever, chills, diarrhea, malaria-like
 - ▶ The treatment of disease by minute doses of natural substances that in a healthy person would produce symptoms of disease
 - ▶ usually provided in alcohol or purified water solution—products are not just ingested
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Efficacy of Homeopathy

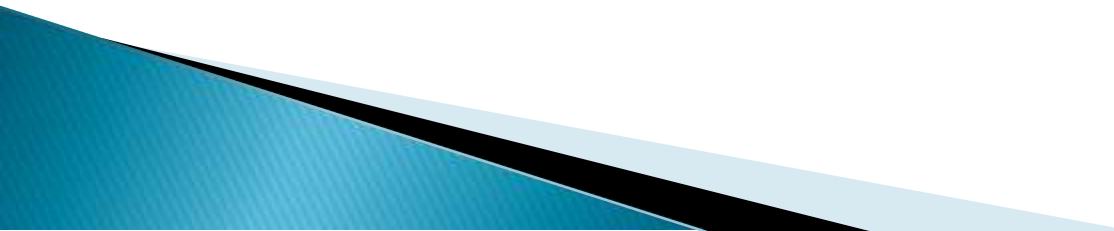
- ▶ Increase in use is dramatic–no longer just a small outlying group
 - ▶ Recent studies: efficacy no better than placebo effect–BMJ, Cochrane, Harvard, etc
 - ▶ Use more frequent in respiratory, ENT, musculoskeletal and pain disorders
 - ▶ Users: more educated than non–users
 - ▶ More benefit when recommended by homeopath vs self–treatment
- 

Case

- ▶ L.O., 10 year old female asthma sufferer,
- ▶ Receiving arsenic album, ipecac sambucus nigra, lobelia inflata as necessary for cough, inability to breathe especially at night
- ▶ School RN identified products when concern arose over child's ability to breathe in class

- ▶ Aqueous arsenic trioxide dilution
- ▶ Ipecac, sambucus nigra
- ▶ Lobelia inflata -pukeweed (Indian tobacco)

FDA Crackdown

- ▶ Homeopathy: teething products which when investigated contained various doses mislabeled belladonna harming babies – banned 2016
 - ▶ Since 1988 homeopathic products mfred and distributed without FDA approval
 - ▶ FDA 2017–scrutinizing homeop. products in certain categories–enforcement where unproven remedies being marketed for serious conditions or diseases
- 

Case

- ▶ 40 y.o. Hispanic Male, DX: OA ACR criteria–VAS pain rating 7–9, usually 5 days a week.
- ▶ Patellofemoral PS on radiograph, no history of secondary OA, 15 lb overweight.
- ▶ Smoker, stage 1 hypertension, BP at home this week—144/94
- ▶ Meds: acetaminophen or Percocet q 6–8 hr, enalapril, hydrochlorothiazide.
- ▶ Has been taking “Botany Bay” to relax when it hurts bad—but it is no longer easy to buy on the internet.

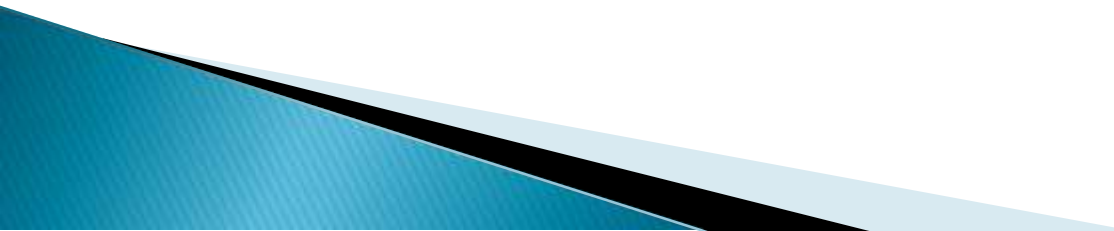
Acquiring info on Botany Bay

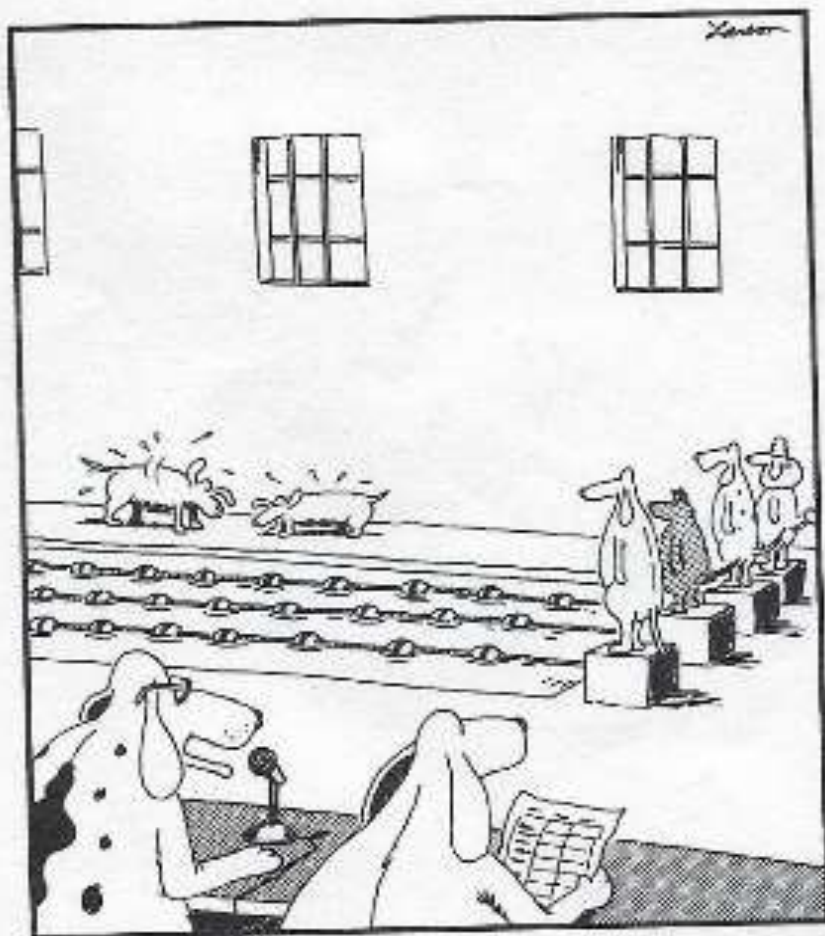
- ▶ Google “Botany Bay supplement”
- ▶ Reuters Feb 21, 2018 – US FDA says recall, destroys certain kratom-containing dietary supps
- ▶ FDA oversees kratom purge after Salmonella outbreak
- ▶ FDA recalls products containing increasingly popular opioid
- ▶ www.ods.od.nih.gov –good choice for example conversations with patients

Botany Bay (kratom)

- ▶ FDA recalled and destroyed kratom containing dietary sup made by Missouri company.
- ▶ Natural plant grown in Asia—to ease pain and reduce symptoms of opioid withdrawal, which critics say can lead to addiction and death
- ▶ FDA has data on numerous deaths– has addictive effects–similar to morphine, has NO therapeutic benefit as dietary sup/ and now is assoc with salmonella outbreak

FDA Crackdown

- ▶ Dietary SUPPS: where serious harm has occurred
 - ▶ --pulling: kratom, DMAA, kava kava, contaminated probiotics, etc.
 - ▶ BUT often the INTERNET continues to allow consumers access to the riskier products
- 



"Well, we're ready for the males' 100-meter freestyle, and I think we can rest assured that most of these athletes will select the dog paddle."


Communication ask-tell-ask

Majority of patients use -- but do not tell us...

H/C pros-identify implicit bias and overcome it....

- why is pt considering this option?
- help patient recognize both sides of the equation
-
- interactions or contraindications
- existing diseases/chronic cond.-Diabetes, cystic fibrosis, heart disease, etc

Communicating risks/benefits

- ▶ Exaggerated claims of “miracle” products—often have hidden interactions
 - ▶ Potential harm— mega—doses
 - ▶ Do not exceed recommended daily allowances of vits/minerals (Ca/Vit D)
 - ▶ Products may not be what they say or seem
 - (heavy metals, Rx, or illegal drugs)
 - ▶ Natural doesn't mean safe
 - ▶ Pregnant, nursing, peds, chronic disease (DM) should be more vigilant
- 

Specific treatments

- ▶ Be concerned when product promoted for disease—by replacing medications, easing blood sugar variations, curing
- ▶ —that is not what dietary supp/herb, etc is supposed to be used for....health claims are not allowed (that would require a New Drug Application)

Fashion is negotiable.
Nutrition isn't.



These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

*Data on file


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Supps / Herbs / Homeopathy for DM

- ▶ Cinnamon (cinnamaldehyde)
 - High doses 1–6gm studied for Bld Sugar lowering and lipid reduction—Pakistani study in 2003 has never been replicated
- ▶ Omega 3 Fatty Acids / fish oil—mixed results
 - Eat fatty fish—or 1 gm/day of EPA/DHA
 - With high triglycerides—value in Rx products
 - Not shown to be beneficial in 2ndary prevention CVD
 - DHA actually increases LDL (1 / 31 / 18 JAMA Cardiology)
- ▶ Garlic – active ingredient—allicin—not possible to eat enough to get effect—supps never been shown to be helpful

Specific treatments

- ▶ Ginseng—no evidence of lipid or blood sugar lowering—may increase/decrease bld sugar
 - ▶ Magnesium— keep levels within normal range— mild supplementation can be helpful
 - ▶ Chromium—can increase metabolism—higher dose than 200mcg per day increase lung cancer risk
 - ▶ Bitter orange—DMAA can increase metabolism—causes respiratory and cardiac stimulation like ephedra
 - ▶ Green tea extract—no evidence that this increases immune benefits over drinking a cup of green tea
- 

Wt Loss / Energy / Performance

- ▶ Products to improve strength or endurance

- Commonly adulterated—seek out FDA alerts

Amino acids, protein, creatine, CAFFEINE and caffeine—amphetamine alternatives to boost metabolism

College kids alone, 2009–2010: 66% reported using some sort of supplement ___20% enhanced muscle strength, 19% performance enhancement, 7% increased endurance

Wt Loss / Energy / Performance

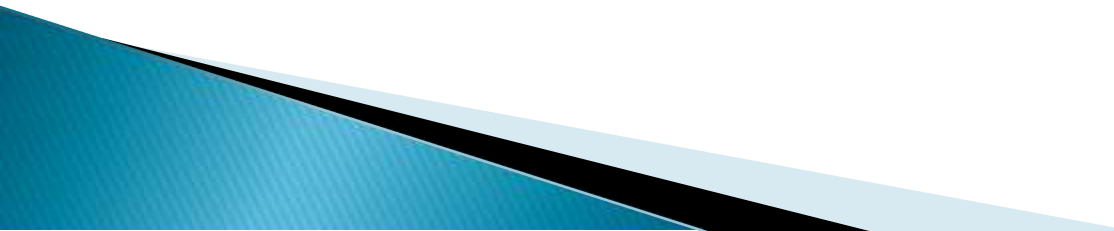
- ▶ Military personnel in 2007–2008
 - Body building in and out of theatre 22.8% M and 5.3% F
- 2011–2012– several soldiers died from DMAA use

Some young people and athletes in general get bad advice from coaches and trainers—H/C profs need to take up these conversations

Many of the substances do work to BOOST metabolism—but often Side Effects or interactions
HARM—heart and respiratory side effects

American Cancer Society Guidelines 2012 to present

NO evidence that phytochemicals taken as supplements are as beneficial for long-term human health as the vegetables, fruits, beans, and grains from which they are extracted.



Case

- ▶ E.G., 74 y.o. female
- ▶ Seasonal rhinitis, dyslipidemia, osteoarthritis in fingers and wrists, hemorrhoids
- ▶ Fluticasone nasal spray BID, Celecoxib 100mg BID, atorvastatin 10mg QD, pramoxine ointment as needed for hemorrhoids.
- ▶ 3 weeks ago, skin started turning yellow, BP increasing, not remembering things, liver transaminase levels elevated
- ▶ Nothing has changed in her life...oh by the way—I am taking a food from the rheumatologist—I need to call the pharmacist for more

Medical Foods

- ▶ Medical Food: food specially formulated for dietary management of disease under supervision of a physician that has distinctive nutritional needs not met by diet alone.
- ▶ Caprylic triglyceride in coconut oil, example for Alzheimer's—unlike dietary supp
- ▶ Limbrel/flavocoxid, plant blend, probably cox 1 and cox 2 inhib—baicalin (from skullcap)/catechin flavonoids creating not just minor serum aminotransferase but acute liver toxicity—acute hepatitis with jaundice
- ▶ FDA banned

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trunature CoQ10 is a smart choice for anyone who wants to help support their heart function, cellular energy production and antioxidant activity.*

*helps support antioxidant activity
and heart function†*

*helps support normal
CoQ10 levels in the blood†*

*helps support cellular
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USP has tested and verified select Kirk and Signature supplements for their ingredients, potency and manufacturing process. USP sets official standards for dietary supplements. See usp.org.

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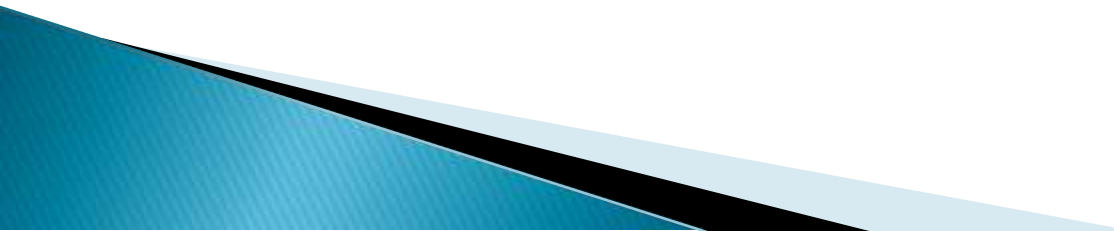
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Sources of Info—ID'ing the facts

- ▶ H/C profs and consumers are getting accurately labeled ingredients ONLY when seal of approval :
 - USPharmacopeia (USP)
 - Consumer lab
 - NSF International
- ▶ False claim—“extremely beneficial to..”, “can treat or cure disease”, “secret ingredient or proprietary blend”, “scientific breakthrough”, personal testimonials, NO RISK STATED or advance payment required

Sources of Info

- ▶ RPh counseling
 - ▶ Avoid purchase from online sources, unless verisign seal of a valid pharmacy in compliance with US drug laws
 - ▶ Internet information—FDA advises against conducting blind searches; instead connect with respected organizations—federal agencies, academic associations, google scholar
- 

Internet sources

www.nccam.nih.gov NCCAM

www.nia.nih.gov National institute on Aging

www.ods.od.nih.gov/factsheets/list-all

Office of Dietary Supplements

www.fda.gov FDA

NIH and National Library of Medicine, medline PLUS, at www.nih.gov

Cochrane/CAM: www.cochranelibrary.com

More internet info

- ▶ National Center for Complementary and Alternative Medicine
 - www.nccam.nih.gov
- National Institute on Aging
 - www.nia.nih.gov
- Office of Dietary Supplements
 - www.ods.od.nih.gov/factsheets/list-all/


Articles that might be helpful

- ▶ Sang MK, et al. Efficacy of omega-3 fatty acid supplements (EPA and DHA) in secondary prevention of CVD. *Arch Intern Med* 2012;172(9)686–696.
- ▶ American Cancer Society Guidelines on Nutrition and Physical Activity for Cancer Prevention, 2012
- ▶ Ashbar BH, et al. Advising patients who use dietary supplements. *Am J Med* 2008;121,91–97.

Articles that might be helpful

- ▶ Owens C, et al. Online Sources of Herbal Product Information. *Am J Med* 2014;127(2),109–115.
- ▶ Diabetes Care.2003;26(12):3215–8.
- ▶ Ann Fam Med.2013;11(50):452–9.
- ▶ Nutrition. 2013;29(10):1192–6.
- ▶ Fortmann, et al. Vitamin and Mineral Supplements in the Primary prevention of CVD and Cancer; An Updated Systematic Evidence Review for the US preventive Services Task Force, Ann Internal Med2013;159(12):824–834.
- ▶ American Pharmacists Assn, www.pharmacist.com Medication and Dietary Supplements: Safe and Effective Care Through Appropriate Product Selection October 2013

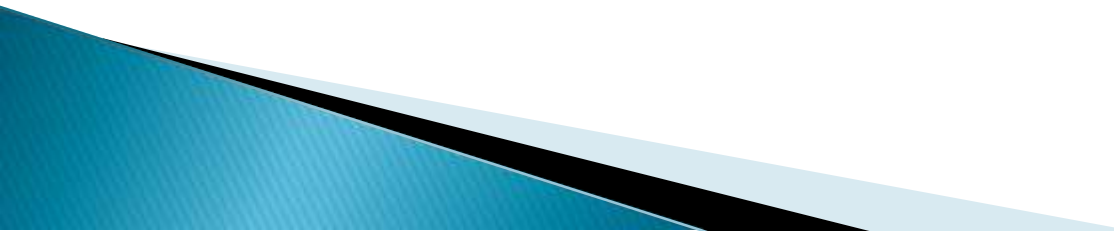
SO.....

- ▶ Herbs, dietary supps, and homeopathy are here to stay....more investigation underway–not paid for by manufacturers.....
 - ▶ Powerful lobbies and wealthy manufacturers are helping to support the myths
 - ▶ Know and use FDA's BeSafeRx campaign to identify and avoid fraudulent online pharmacies
 - ▶ Verisign seal –USP seal
 - ▶ Learn all you can
- 



"Oh boy! ... It's dog food again!"

Post test

- ▶ Patients feel more comfortable disclosing product use information to physicians who:
 - ▶ 1. have little time to chit chat
 - ▶ 2. show a judgmental approach to discussing supplements and the lack of proof associated with their use
 - ▶ 3. show an honest attempt at assisting patients in finding out facts about various treatments
- 

- ▶ Anyone who doesn't think there are two sides to an argument, is probably in one—
 - Unknown