



PARKINSON'S AND HERBAL SUPPLEMENTS

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OBJECTIVES

- What is the difference between herbal supplements, over the counter medicines, and prescription medicines?
- Things to look at when considering herbal supplements
- Common supplements in PD



SPOT THE DIFFERENCE: RX, OTC, AND HERBALS



WHAT IS A PRESCRIPTION MEDICINE?

- Pharmaceutical drug that requires provider oversight via dispensing with prescription
 - Potential for misuse: drug abuse potential, practicing medicine without a license and without proper education
- Products and advertising are regulated by the Food and Drug Administration
 - Required to go through approval process and provide proof of efficacy and safety before it can be marketed
 - Highest level of regulation

WHAT IS AN OTC MEDICINE?

- Sold directly to us without a prescription
- Used to treat conditions that do not need the care of a healthcare profession (i.e. appropriate for self-medicating)
- Products are regulated by the FDA and contain an approved “Drug Facts” labeling; advertising is regulated by the Federal Trade Commission
- Examples
 - Any items with therapeutic effect- sunscreens, certain anti-dandruff shampoos, creams/lotions
 - Lower doses of prescription medicines (i.e. ibuprofen)
 - Prescription medicines that applied to become OTC with sufficient data (i.e. Claritin[®], Prilosec[®])


WHAT IS A DIETARY SUPPLEMENT?

- A product taken by mouth that is intended to supplement the diet and that contains one or more “dietary ingredients”, which may include
 - Vitamins
 - Minerals
 - Herbs or other botanicals
 - Amino acids
 - Other substances such as enzymes
- Not intended to treat, diagnose, cure, or alleviate the symptoms of diseases
- Least regulated- NOT approved by the FDA, some oversight once drug is on the market



SUPPLEMENTS: BE SAFE, BE INFORMED





“...the more than \$30-billion supplement industry is largely regulated by the honor system, and not the FDA.”

REGULATIONS

- Dietary supplements must...
 - Be labeled as a dietary supplement, herbal supplement, or similar wording
 - Include “Supplement Facts” label listing ingredients
 - Report serious adverse events
- But they don't have to...
 - Prove safety before marketing
 - Prove that claims regarding the product are accurate or truthful before marketing
- **Following** introduction to the market, the FDA monitors safety events, and reviews product labeling/information as resources permit. The FTC monitors advertising as resources permit.



Government lawsuit disputes "extravagant" claims of memory ...

CBS News - Jan 10, 2017

A new lawsuit by two government agencies accuses the company behind dietary supplement **Prevagen** of misleading its customers.

Memory-boosting supplement **Prevagen** has no scientific backing ...

STAT - Jan 9, 2017

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Stop using **Hydroxycut** products, **FDA** says

CNN - May 1, 2009

Stop using **Hydroxycut** products, **FDA** says ... linked to liver damage and are being recalled, the U.S. Food and Drug Administration said Friday.

Hydroxycut products recalled after one death: **FDA**

Reuters - May 1, 2009

FDA Recalls Diet Pill **Hydroxycut** After Reports of Liver Damage ...

FOXNews - May 1, 2009

Hydroxycut Recall Due to Liver Injuries

WebMD - May 1, 2009



Airborne Settles Suit over False Claims

NPR - Mar 8, 2008

Makers of the herbal supplement **Airborne** have agreed to pay \$23.3 million in a class-action lawsuit over false advertising. David Schardt, a ...







Undeclared Drug Leads to **Recall** of Natural Male Enhancement ...

Pharmaceutical Processing - Sep 22, 2017

Natures **Supplement**, Inc. is voluntarily recalling 260 bottles of Vegetable Vigna, 200 mg capsules to the consumer level. **FDA** analysis found ...

QUALITY

- Certification is optional, and they test to make sure the label matches the ingredients only
- Many supplements do not seek certification due to cost and likely lack of incentive
- A 2015 study showed that only 21% of products had the ingredients on their labels

	 CONSUMERLAB.COM	 NSF INTERNATIONAL	 U.S. PHARMACOPEIA (USP)	 UL
Does it buy initial test samples in stores or are they provided by the manufacturer?	Purchased in stores.	Provided by the manufacturer.	Provided by the manufacturer.	Provided by the manufacturer.
How often does it retest or spot-check?	Once per year using samples purchased in stores.	Once per year using samples provided by manufacturer and occasionally purchased in stores.	One to six times per year using samples purchased in stores.	Twice per year using samples purchased in stores.
How much do manufacturers pay to have each product certified?	\$3,000 to \$5,000 per product.	\$3,000 to \$5,000 per product plus an audit fee of about \$13,000.	\$3,000 to \$15,000 per product plus an initial audit fee of \$15,000 and a label fee of 1 cent per bottle.	\$2,000 to \$8,000 per product plus an audit fee of \$4,000 to \$7,000.
Are there products it won't test?	Products containing ingredients known to be unsafe.	Products marketed for weight loss or sexual enhancement.	Products known to contain unsafe ingredients and those marketed for erectile dysfunction, weight loss, or sports.	Products containing ingredients known to be unsafe or those not recognized as dietary ingredients by the FDA.

SAFETY

- Drug Interactions
 - St John's Wort, a supplement commonly used for depression, has good data to support its use, but it can interfere significantly with the levels of oral contraceptives, immunosuppressants, certain cancer drugs, and many others
- Adverse Effects
 - In patients who may have an elevated risk for bleeding, ginkgo can cause spontaneous bleeding
- Toxicity
 - Butterbur, a supplement with data for use in migraine prevention, can be toxic to the liver if a certain component is not removed from the product

EFFICACY

- Can be difficult to distinguish between the marketing and the facts
- Studies are often conducted by the people trying to sell it to you, have few patients and aren't scientifically sound
- With no requirement to prove efficacy, manufacturers don't have motivation to conduct structured, rigorous research
- Traditional herbs that have been around for centuries may have the best data, but as interest grows, research will grow too



COMMON SUPPLEMENTS IN PD



SUPPLEMENTS STUDIED IN PD

- Antioxidants: Vitamin C, Vitamin E, Mediterranean Diet
- Calcium/Vitamin D
- Coenzyme Q10
- Ginger
- Gingko Biloba
- B vitamins (folate, B12, B6)
- Green Tea Polyphenols
- Marijuana
- Milt Thistle
- St John's Wort
- Mucuna Pruriens (aka velvet bean)

B VITAMINS

- Claim: B12 deficiency is common in PD, and B6 may decrease risk for PD.
- Quality: Is this available from a quality source?
 - Yes, certified brands such as Kirkland have B vitamins
- Safety: Are there any adverse effects or drug interactions that I should be concerned about?
 - Too much B6 can cause painful neuropathies so monitor these amounts, otherwise no.
- Efficacy: Is there data to support me using this?
 - Yes, studies show that B12 deficiency is more common in PD patients. Data regarding B6 is not as strong. We are able to check vitamin levels to monitor the supplement's effectiveness and safety.
- **Yes, we can safely recommend use of B vitamins in appropriate patients.**

MUCUNA PRURIENS/VELVET BEAN

- Claim: Mucuna is a natural source of levodopa (with other things) that can help with on-off fluctuations and dyskinesia.
- Quality: Is this available from a quality source?
 - No certified sources available. We cannot be sure if the source product contains what the label says or in the amount the label says.
- Safety: Are there any adverse effects or drug interactions that I should be concerned about?
 - Dyskinesias are possible, as well as other side effects from levodopa. The other components of the supplement can lead to unknown side effects.
- Efficacy: Is there data to support me using this?
 - Small, single dose studies suggest there could be a benefit, but there is no good long term data with lots of patients.
- **No, we cannot safely recommend use of mucuna pruriens.**

MARIJUANA

- Claim: Marijuana can be neuroprotective and help with PD motor and non-motor symptoms.
- Quality: Is this available from a quality source?
 - Product can vary greatly, even among dispensaries that carry “medical grade” marijuana. Percent makeup of the marijuana, in terms of which THC (produces the “high”) and CBD components are present, is not regulated at this time. There are limitless strains of marijuana available, with variations in the components.
- Safety: Are there any adverse effects or drug interactions that I should be concerned about?
 - Marijuana does present drug interaction potential as it can interfere with some of the enzymes that break down medications. Side effects can vary based on the formulation (edible vs. smoked) and amount of THC/CBD making it impossible to predict any specific person’s response at this time. Harm of long term use is not well known.
- Efficacy: Is there data to support me using this?
 - Data in this field is growing, and is more impressive in some areas than others. Data in Parkinson’s Disease at this moment is inconsistent and not sufficient to recommend use.
- **No, we cannot safely recommend use of marijuana.**

THE BOTTOM LINE

If you are considering use of a supplement, involve your healthcare team ***before*** you start the product.

QUESTIONS?

