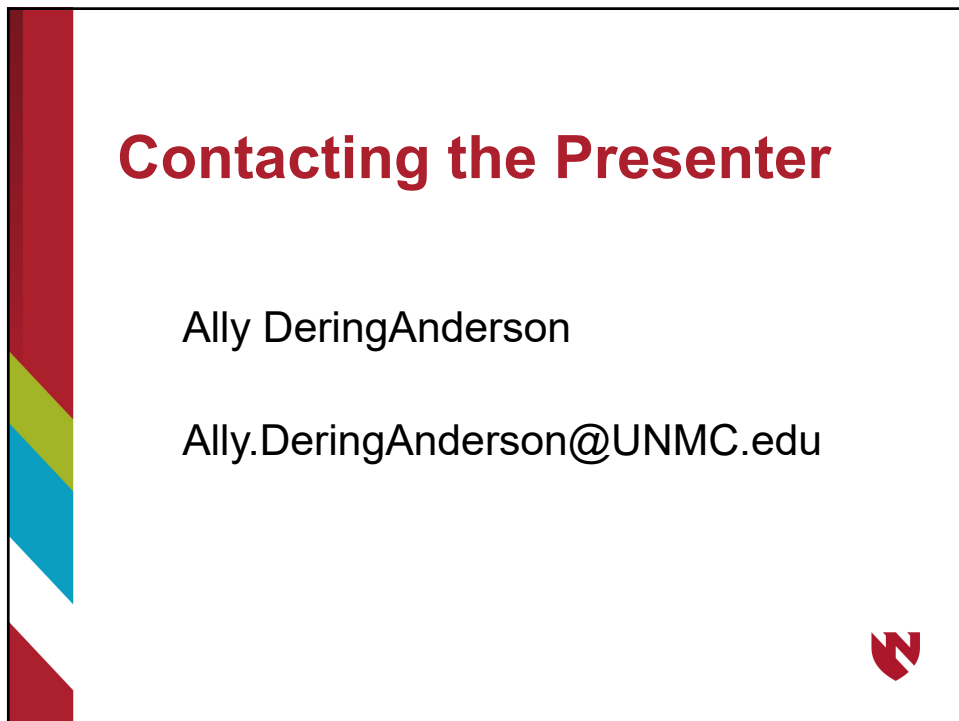


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## Disclosures and Conflicts

I am employed by the University of Nebraska College of Pharmacy and I receive a salary from them. I do research and scholarship as a part of my job and these are funded through a variety of sources.

I am the senior partner in BBfN, LLC; A Health and Safety Consulting Company

I am a consultant for 2 same-day Surgical Centers. These surgery centers pay a discounted hourly wage directly to an account in the Department of Pharmacy Practice at the University of Nebraska College of Pharmacy for this service and the Surgery Centers allow PharmD students to accompany me on consulting visits.

I am the Chairman and serve on the Nebraska Medicaid Pharmacy and Therapeutics Committee. I am paid mileage to attend these meetings.

I do not accept speaker's funding directly from any member of the drug manufacturing or distribution industry. My programs may be indirectly funded by these entities, but I do not solicit such funding on behalf of anyone. Furthermore, it would be impossible to buy my opinions, you will recognize that as fact before the completion of this program.

My spouse, my parents and my adult children all participate in the stock market and own individual stocks. I do not know which stocks they own at any given time. I can assure this audience that no member of my family nor combination of members of my family own 1% or more of any publicly traded company.

Several members of my family belong to professions credentialed by the Nebraska Department of Health & Human Services or the corresponding Departments in other states including: Missouri, Kansas, Iowa, Oklahoma, and Colorado. My husband is a hydro-geologist, my father is a pharmacist, our daughter is a pharmacist, our son is a fitness trainer, my brother is an athletic trainer. Additionally, I have a maternal uncle who is a pharmacist and we have a daughter-in-law who is a nurse. At present the only member of my family other than me, who holds a health credential and lives in my home is my husband.

I have filed the necessary paperwork with the University of Nebraska and the State of Nebraska to meet the Sunshine Law. You are welcome to access my information on their respective web-sites. My full and legal name is: Allison Mari Dering-Anderson



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## Today is 6 October 2023

There may be a discovery or a publication tomorrow that changes the information presented today!

That's the joy of science, it's not static and it requires that you change your mind as you gather new information and evidence.



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## Learning Objectives

At the completion of this program, the alert attendee should be able to:

- Discuss dietary supplements as a part of a medication review and reconciliation
- Describe the regulation of dietary supplements
- Identify that “labeling” or “off label use” are not concepts that apply to dietary supplements as they do for traditional drugs



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## DSHEA

Allows the FDA to remove dangerous products from the market when a sufficient number of deaths or serious injuries are discovered.

Prohibits the FDA from requiring safety studies **before** marketing

Prohibits the FDA from requiring efficacy studies **before** marketing

Gives the FDA very limited authority regarding labeling



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## What Works?

Cranberry Juice  
Aloe Vera  
Horny Goat Weed  
Lavender



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## Vaccinium oxycoccos (Cranberry)



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## cranberry

The berry & leaves are used medically:  
Fresh, juiced, dried

Indigenous American used cranberry for:  
bladder, stomach, liver, diabetes,  
wounds, paints, and dyes

Current claims:  
UTI prevention & treatment  
diabetes



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## cranberry

Evidence:  
no evidence for existing UTI

In 2020, the U.S. Food and Drug Administration announced that it would permit manufacturers to claim on product labels that there is “limited” evidence that daily consumption of specified amounts of cranberry dietary supplements may reduce the risk of recurrent UTI in healthy **women** who have had a UTI. A similar claim may be made for cranberry juice beverages, but the evidence must be described as “limited and inconsistent.”



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## cranberry

### Safety

Richly colored fruit is a part of a well-balanced diet

Diarrhea reported in children who are supplemented



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## But, the label says ...

But, the label isn't

- Approved
- Except for very specific prohibitions, regulated

The label is

- Pretty enough to make you take it off the shelf
- Intended to help sell the product



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## Aloe vera



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## Aloe Vera

The fleshy leaves of the plant are used

Historic uses for skin conditions and wound healing - - not consumed orally historically

Current claims

Topical: acne, lichen planus, burning mouth syndrome, burns, radiation-induced skin toxicity

Oral: weight loss, diabetes, hepatitis, inflammatory bowel diseases, constipation\*



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## Aloe vera

### Evidence:

No evidence of efficacy when consumed orally  
Aloe gel + medical soap + tretinoin improve acne  
Improved healing after burns with decreased pain

### Safety:

Some reports of topical sensitivity  
oral use can cause abdominal pain, cramping, acute hepatitis  
oral use can cause digoxin toxicity  
do not take by mouth when pregnant or breast feeding



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## Epimedium (Horny Goat Weed)



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## Horny Goat Weed

Stems, Flowers, and Leaves are used

Historically used as a treatment for male sexual dysfunction and female low libido

Current claims

“natural Viagra”; osteoporosis; bronchitis; PMS



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## Horny Goat Weed

Evidence

icariin is a minor PDE<sub>5</sub> blocker – may help with erectile dysfunction, may be synergistic with other PDE<sub>5</sub> blockers

phytoestrogens may slow osteoporosis

Safety

appropriate dosing in adults appears to be safe

Cautions: high doses have been linked to renal and hepatotoxicity; do not use with endometriosis, uterine fibroids, breast cancer; anticoagulant therapy; prior to surgery



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## Lavandula (Lavender)



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## Lavender

Essential oil is used in aroma therapy, food flavoring, soap, cosmetics, medicine

Used in Greece and Rome for aroma, calming, skin care

Current claims

Aroma – insomnia, calming

Topical – wound care



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## Lavender

### Evidence

aroma therapy calming in Intensive Care,  
before chest tube removal,  
preoperative anxiety  
no evidence of sedation  
no evidence of benefit on skin lesions

### Safety?

Essential oils are highly concentrated can  
cause tissue damage (**Aroma therapy**)  
Consumption as a flavoring appears safe



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## Monitoring Plan

If there is no conversation, there is no  
monitoring

ASK specifically about herbal products or  
dietary supplements

ASK your pharmacist or pharmacist intern  
about any supplements you are taking



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## WHY?

Please, tell me about this choice

How much do you take?

Where do you get it?

How long have you been doing this?

Does it help?



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## What Doesn't?

Ashwaganda  
Black Cohosh  
Cinnamon  
Echinacea  
Saw Palmetto



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## Ashwaganda

A part of Ayurveda

You either practice all Ayurveda or you don't.

Putting eggplant and olives on your jumbo fried burger doesn't make it a Mediterranean diet!



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## Turmeric (curcumin)

Also a part of Ayurveda

As a spice, particularly in curry, curcumin is very important

No identified health benefits with evidence of efficacy

Very low bioavailability (doesn't get out of your gut well)

National Center for Complementary & Integrative Health;  
National Institutes of Health



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## Actaea racemose (Black cohosh)



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## Black Cohosh

A flowering plant, related to the buttercup

Used since ancient times for  
 musculoskeletal pain and spasms  
 calming  
 improving tone in the kidneys and uterus  
 menstrual cramps

Also called:

Black bugbane  
 Black snakeroot  
 Fairy candle  
 Macrotys  
 Rattleweed  
 Rheumatism Weed



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## Current use for Black Cohosh

Today we use the roots and underground stems

To treat  
 anxiety  
 hot flashes  
 profuse sweating

Minimal evidence for anxiety  
 NO EVIDENCE for hot flashes, profuse sweating



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## Black Cohosh

### Side Effects

Breast pain  
 Gynecomastia  
 Cramping  
 Headache  
 Weight gain  
 Muscle pain  
 Rash  
 Gastric distress  
 Vaginal spotting

### Cautions / Contraindications

liver disease  
 pregnancy  
 lactation



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# Cinnamon



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# Cinnamon

Cinnamon, as used in cooking comes from the bark. Leaves, flowers, fruits and roots have also been used historically in medicine

*Cinnamomum verum* (Ceylon cinnamon) grows primarily in Sri Lanka and is the cinnamon in many ancient medicine references

*Cinnamomum aromaticum* (Cassia cinnamon) appears most often in the United States



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## Cinnamon

### Current claims

- use for lowering blood sugar
- use for irritable bowel syndrome
- use topically as an insect repellent

### Evidence?

None

Studies claiming to show benefit in reducing blood sugar are poor studies, many don't describe the type of cinnamon, etc.



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## Cinnamon

### Safe?

- At doses used in cooking cinnamon is safe
- At larger doses cinnamon can cause gi symptoms
- Orally and topically cinnamon can cause allergic reactions

NCCIH\* publishes a warning not to forego conventional medical care in favor of cinnamon

\*National Center for Complementary and Integrative Health



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## Echinacea



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## Echinacea

The root is used medically in tablets and tinctures  
The leaves and flowers are used in herbal teas

History of use in indigenous Americans, the plant is native to North America often used for wounds and skin eruptions

Current claims:

Treatment of common cold and other respiratory conditions



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## Echinacea

### Evidence?

Potential for a slight reduction in the chance of “catching” a rhinovirus

No other evidence of benefit – does NOT reduce duration or intensity of a rhinovirus infection

### Safety

Uncertain safety during pregnancy or breast feeding

Side effects – nausea, stomach pain

Allergy is common - can be severe



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## Serenoa repens (Saw Palmetto)



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## Saw palmetto

Native to the southeast United States – historically used for cough and reproductive disorders

Berries and seeds from the plant are used medicinally

Current claims are for

- BPH
- urinary difficulty
- hair loss
- chronic pelvic pain



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## Saw palmetto

Evidence:

NIH funded 2 large, high-quality studies that demonstrate no benefit over placebo

Safety:

- Safety unknown in pregnancy and breast feeding
- Does not appear to impact PSA testing
- May cause nausea and headache



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## What is Concerning?

Ginseng  
Guarana  
Kava Kava  
Cannabinoids



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## Panax (Ginseng)



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## Ginseng

The root of the plant is used medically

Ginseng has been a part of Chinese  
medicine for 1000's of years for  
overall health  
stamina  
to improve concentration and memory



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## Ginseng

Current claims:

Memory / Alzheimer's  
premature ejaculation (topical)  
anxiety

Evidence?

none



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## Ginseng

### Safety

Most common side effect is insomnia

Should not be used in children

do not use if pregnant (teratogen in rodents) or breast feeding



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## Paullinia cupana (Guarana)



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## guarana

Seeds and juice of  
seeds are used  
medicinally

Contains stimulants: caffeine, theophylline,  
theobromine

Historically used for stimulant beverages  
no medicinal uses noted from the Amazon



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## guarana

Current claims

Mostly found in “energy drinks” and  
weight loss products

May be included to “disguise” the  
stimulant content



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## **Piper methysticum (Kava / Kava Kava)**



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## **Kava**

The root is used medicinally and in religious services

The Polynesian religions using kava use it to talk with their higher power in visions

Routine or daily use of Kava is not common in the Pacific islands



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## Kava

### Current claims

insomnia  
anxiety

### Evidence

Does cause sleep when mixed with rum  
in religious ceremonies



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## Kava Kava

### Safe use –

other than religious practices **NONE**

**hepatotoxic**

**kava dermopathy with jaundice**

**dizziness**

**habit forming**



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## Cannabinoids

CBD is very sedating

Chronic use of whole plant can dramatically increase the doses needed to achieve anesthesia

Multiple drug-to-drug or drug-to-disease interactions



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## The biggest concern with dietary supplements

Foregoing recommended pharmacotherapy in favor of unproven, virtually unregulated product.

Other concerns:

- Expensive

- Drug to Drug Interactions

- Toxicity

- Interference with lab results



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**Questions?**

**Comments?**

**Concerns?**



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