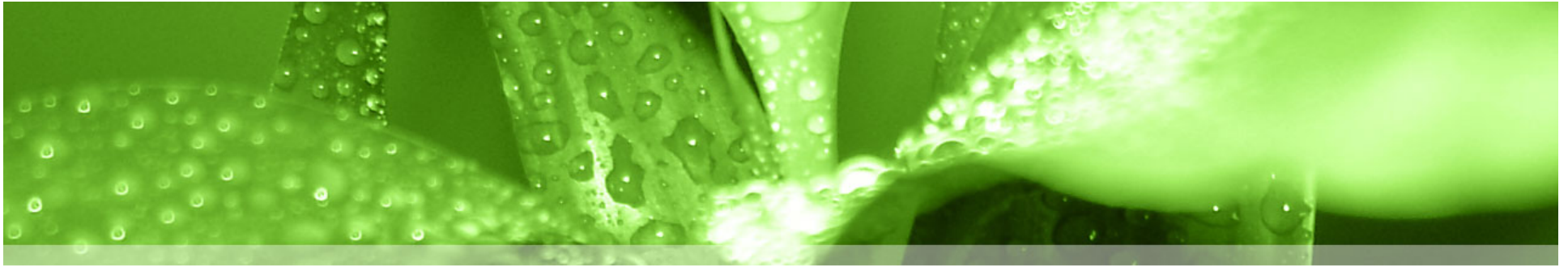


# cancer answers

Cancer Answers is a series of free public lectures, presented by *Cancer Care Nova Scotia*, on a variety of cancer-related topics. The lectures, delivered by cancer experts, are designed to raise awareness and educate participants about issues related to prevention, screening, early diagnosis, treatment, survivorship and palliative care.

Following each lecture, the presentations are posted on the *Cancer Care Nova Scotia* website.





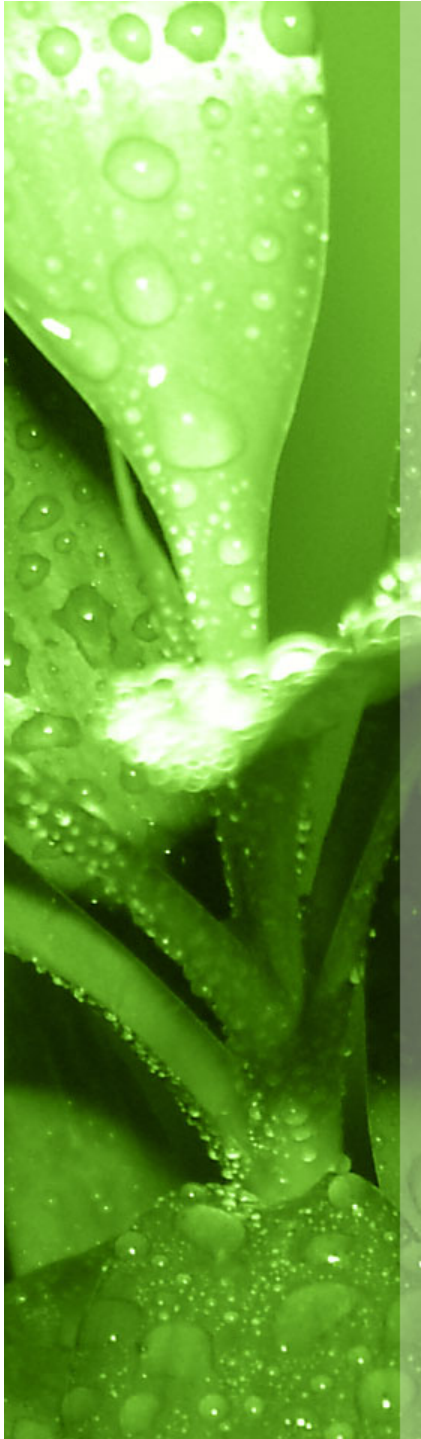
# **Complementary and Alternative Therapies (Part II) : Making informed decisions on "natural products" and Cancer Care**

**November 18, 2008**

Debbie Saulnier, BScPharm, ACPR

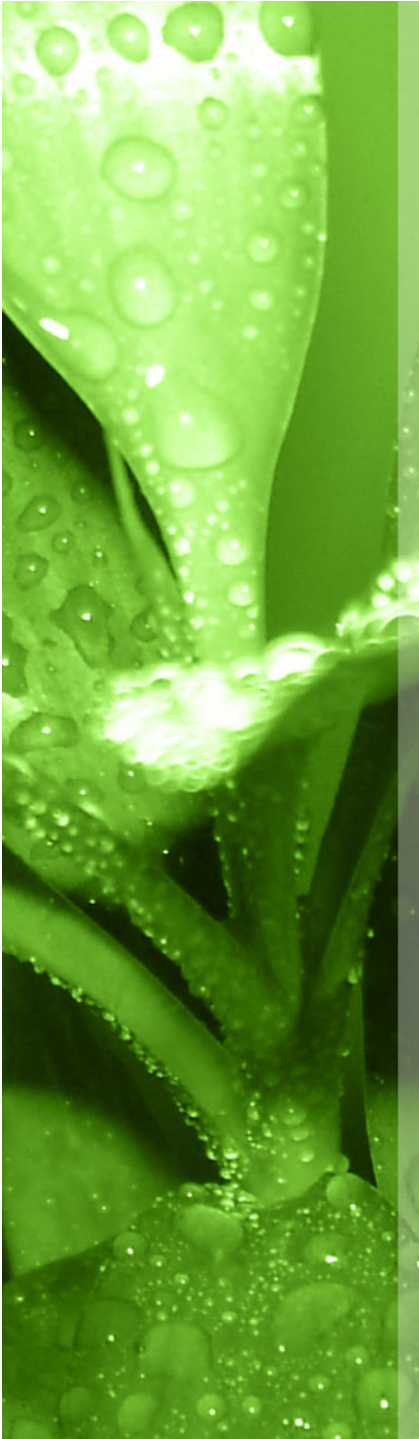
Oncology Pharmacist, Capital Health Cancer Care Program





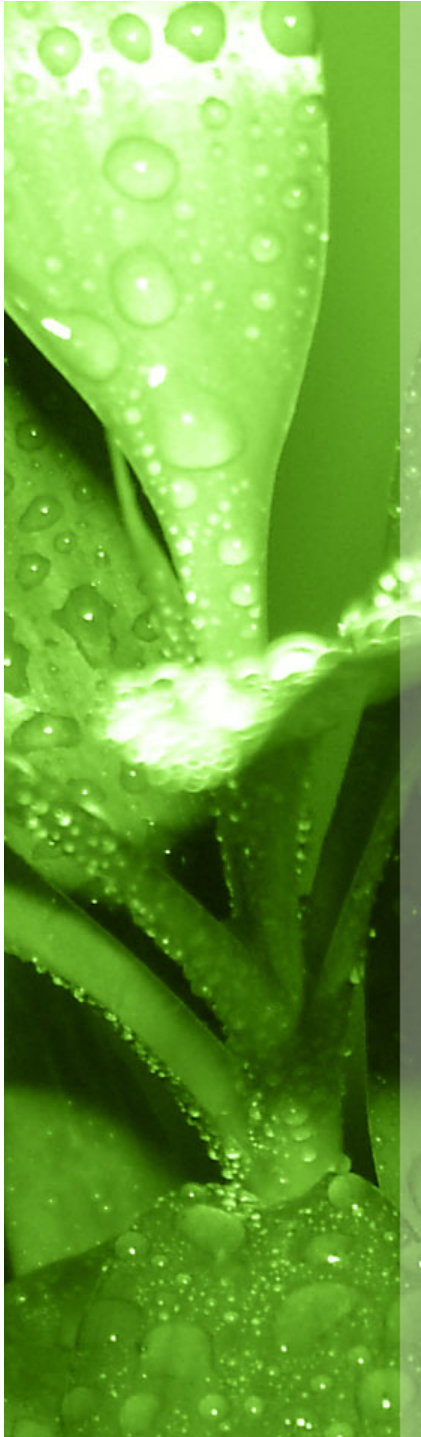
# Outline

- Health in the 21<sup>st</sup> Century
- What are Natural Health Products?
- Regulation of Drugs/Natural Products
- Natural Products and Cancer
- Are Natural Health Products right for you?
- Potential Interactions
- Where to find information
- Examples



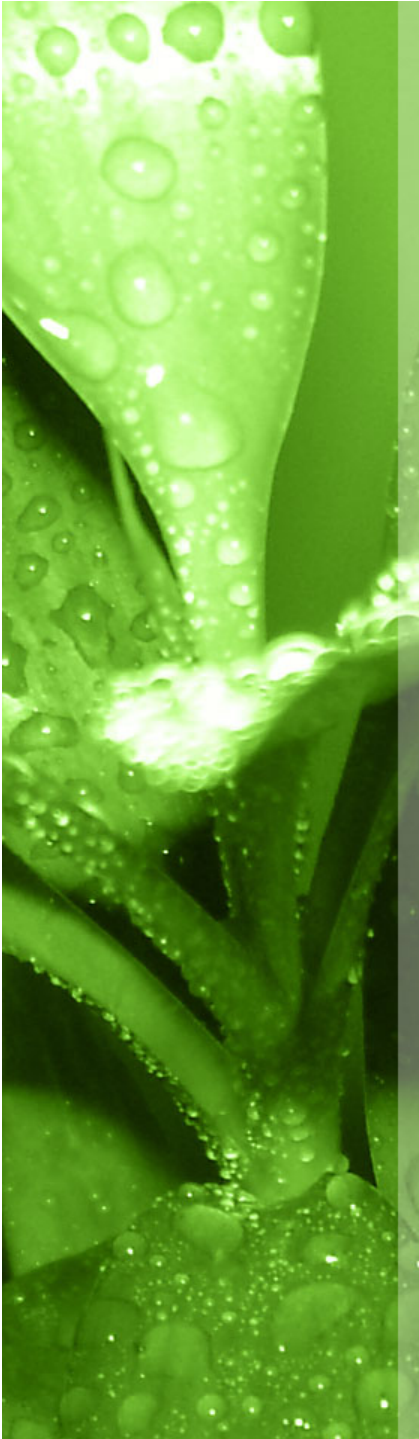
# Health in the 21<sup>st</sup> Century

- New Discoveries
- Questioning safety:
  - ▣ Plastics (BPH – Bisphenol A)
  - ▣ Pesticides/Chemicals
  - ▣ Product testing
- Patient Centered Care



# Natural Health Products

- Complementary vs Alternative medicine
- Herbs, vitamins, minerals, other supplements (aminoacids, essential fatty acids)
- Homeopathic medicine, Traditional Chinese Medicine, Probiotics

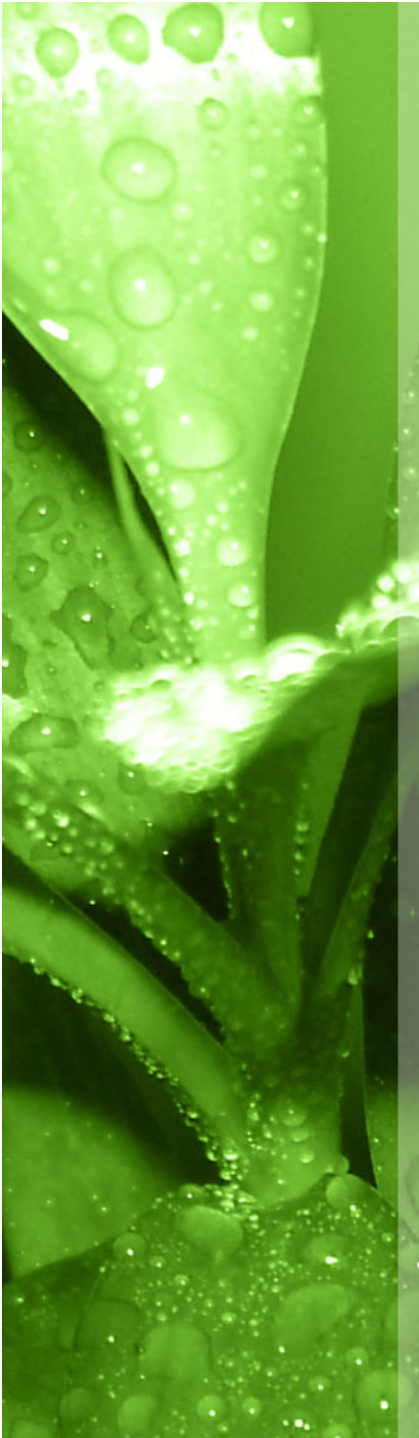


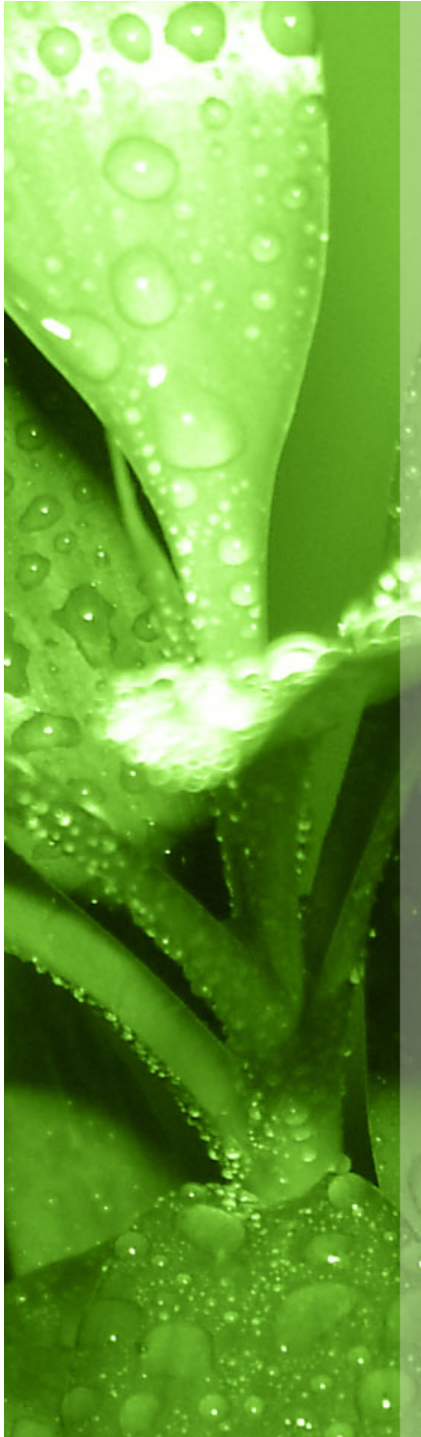
# Natural Health Products

- ❑ Drugs: any **chemical** substance, that when absorbed into the body of a living organism, alters normal body function
- ❑ Medicinal Herbs: phyto**chemicals** that have effects on the body
- ❑ Herbal products are natural **drugs**
- ❑ Natural  $\neq$  Safe

# Grecian Foxglove

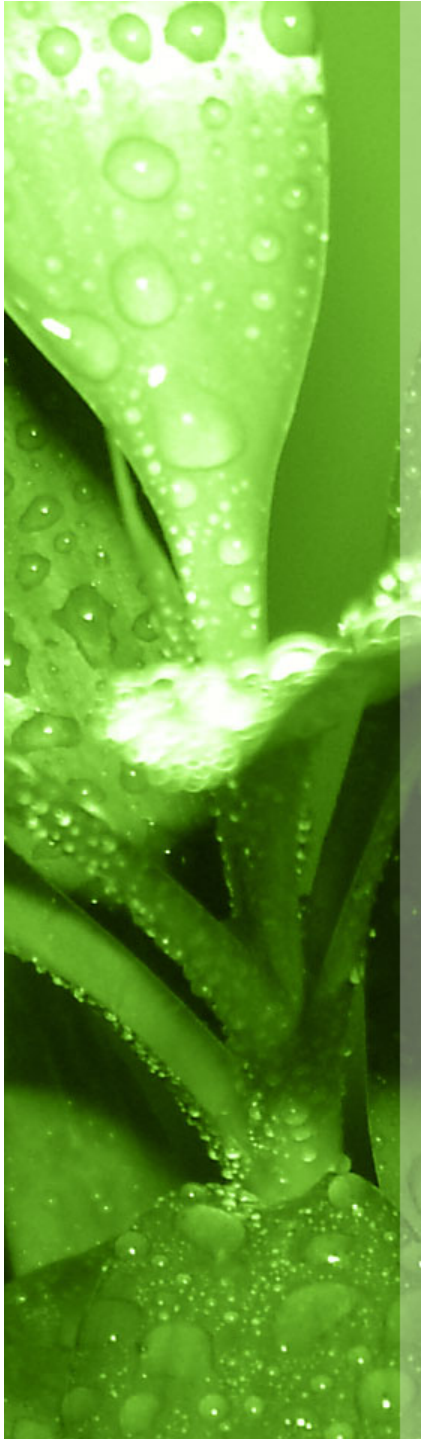
- *Digitalis lanata*
- Used in modern medicine as a “Heart Medication” ~ Digoxin (Lanoxin®)
- Entire plant is poisonous
  - Dead Man’s bells, Witches gloves
- Many side effects
- Small difference between helpful dose and toxic dose





# Canadian Regulations

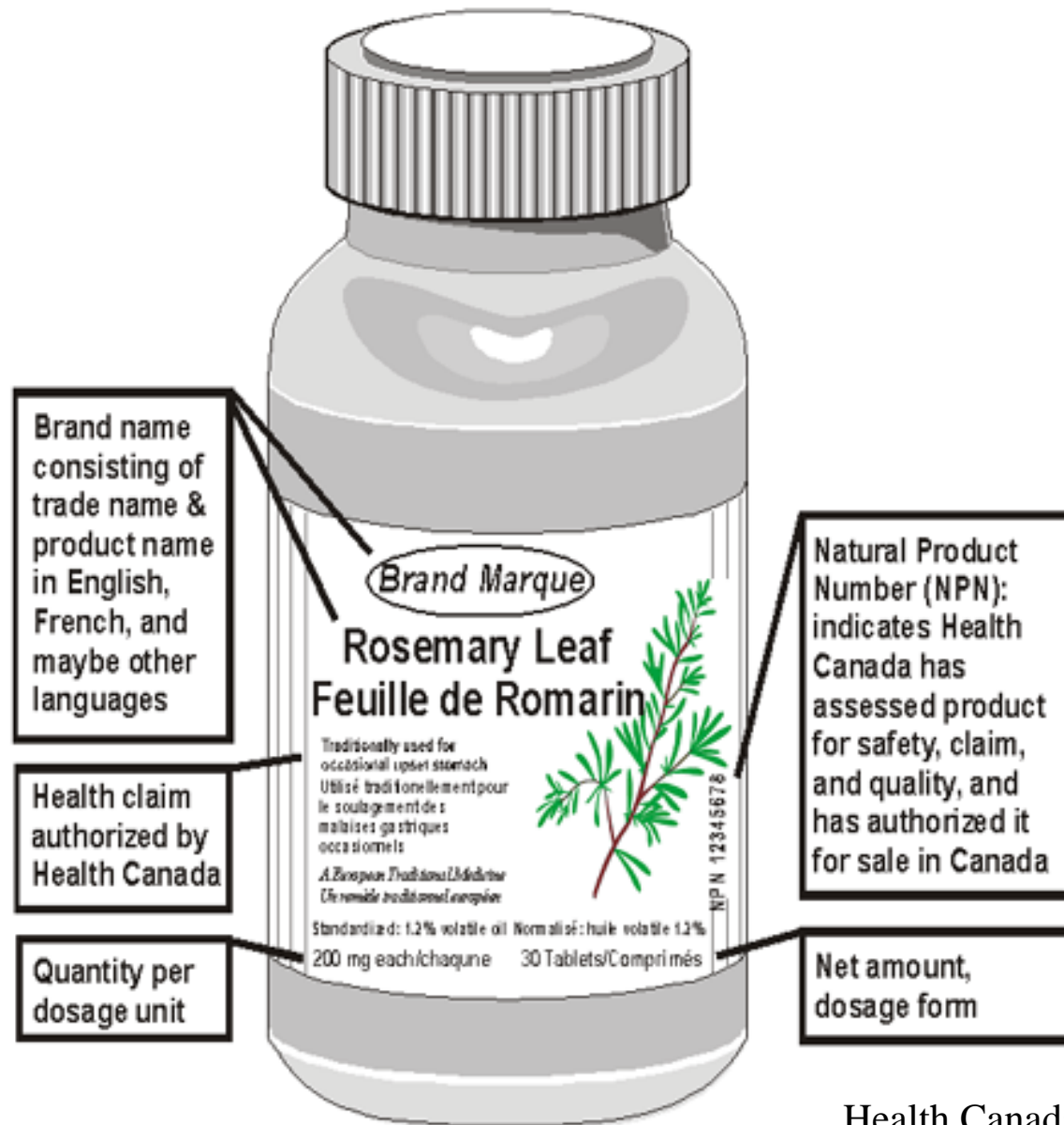
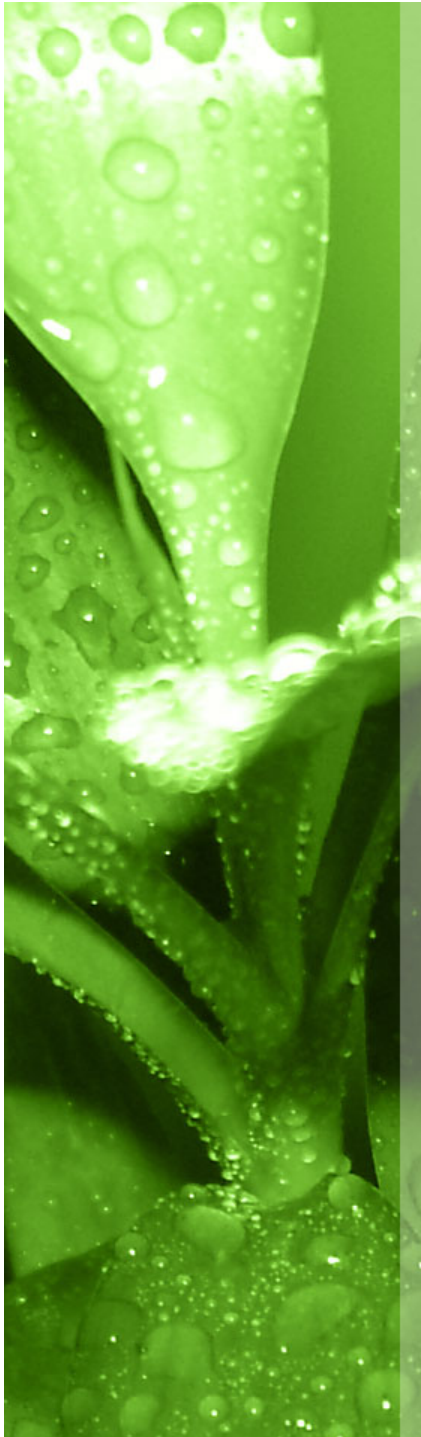
- Food and Drugs Act
- Natural Health Product Regulations
- Why?
  - Ensure ready access to NHP's that are safe, effective, high quality
  - To prevent.....
    - completely unfounded health claim's
    - Products containing prescription drugs
    - Contaminants

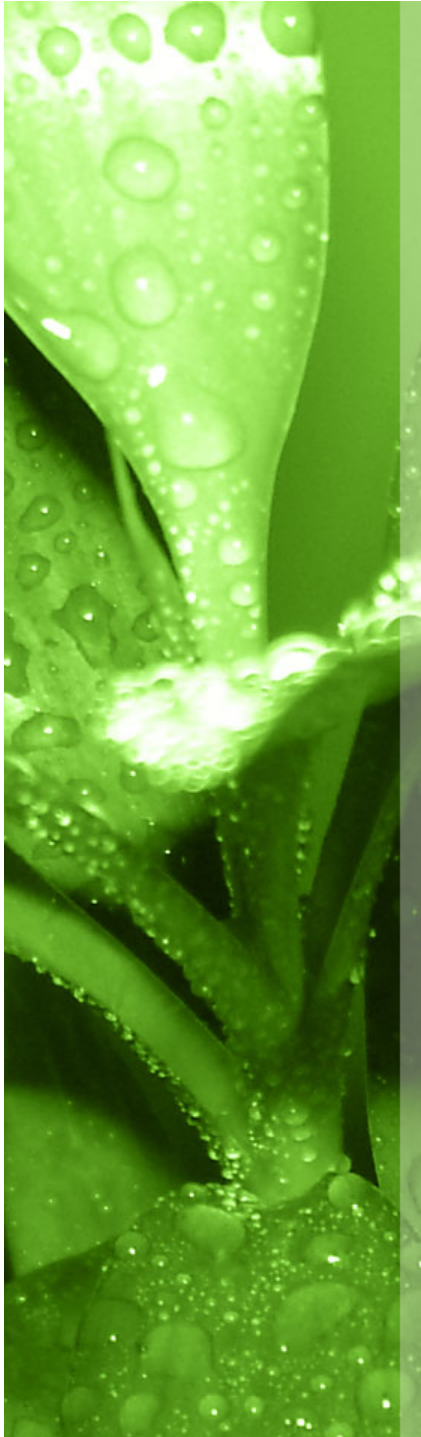


# Natural Health Product Regulations

- Started Jan 1, 2004
- 2-6 year transitional period
- NPN number (or DIN-HM) – once authorized for sale in Canada by the Natural Health Products Directorate

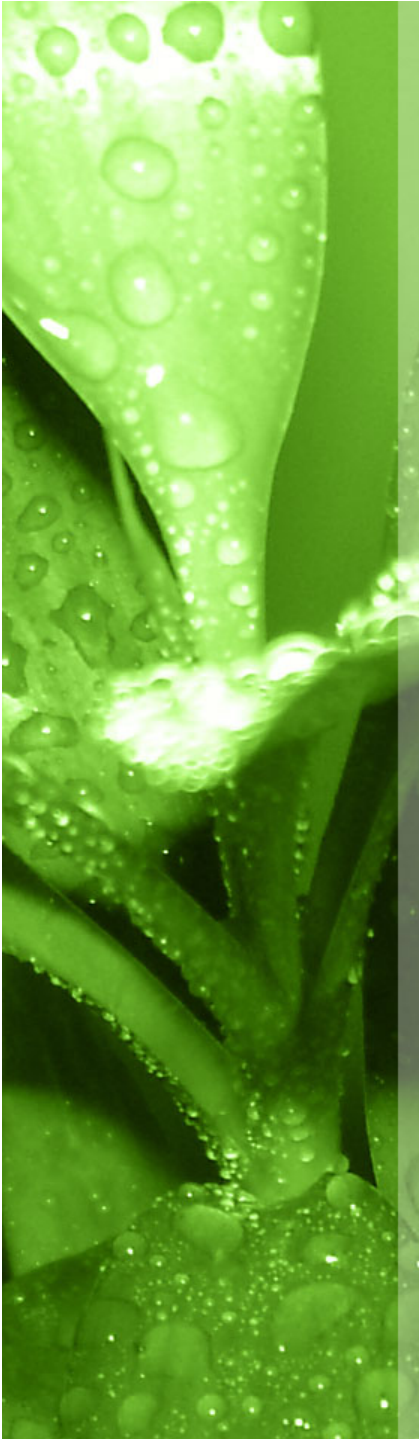
# Canadian Regulations





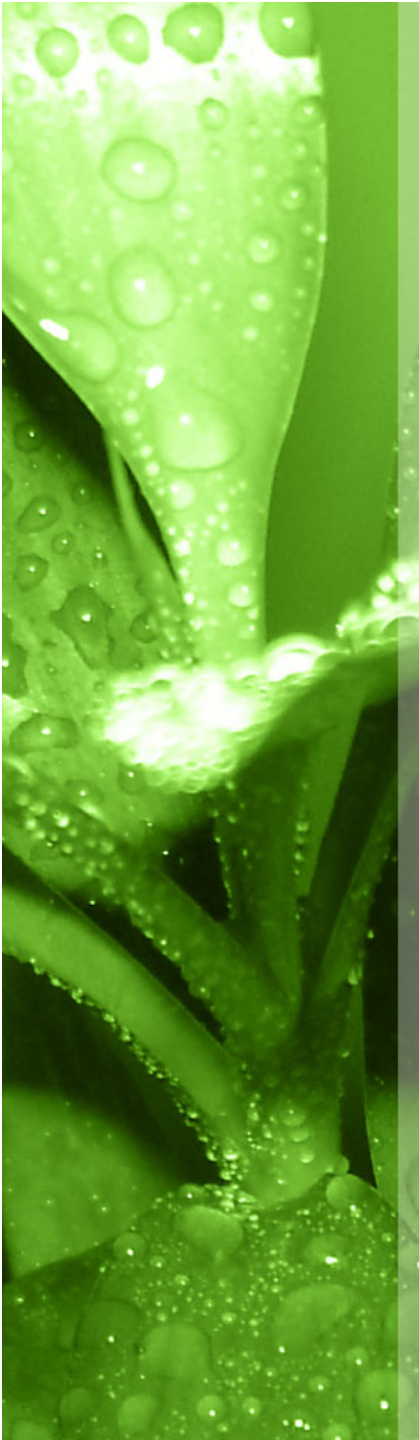
# Natural Health Product Regulations

- Good Manufacturing Practices (Places, People, Processes, Products)
- Packaging/labelling
- Importation and distribution
- Evidence for use
  - Traditional claim
  - Non-Traditional claim

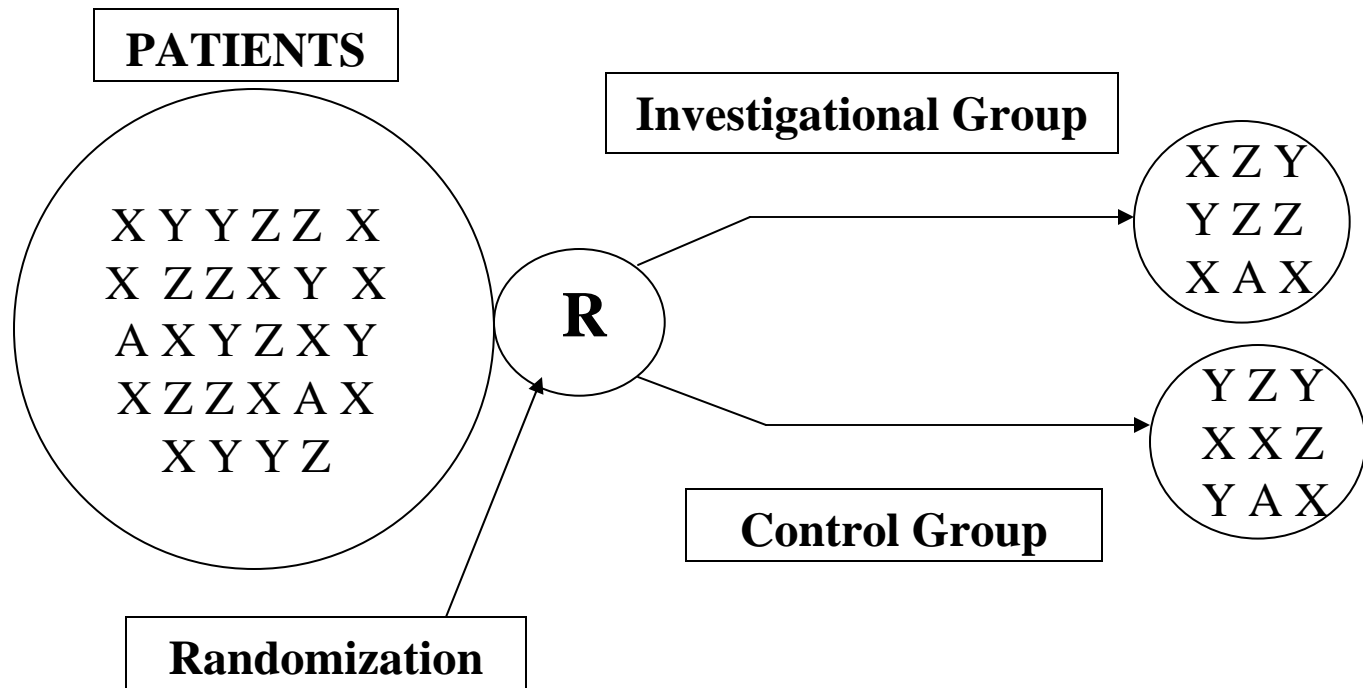


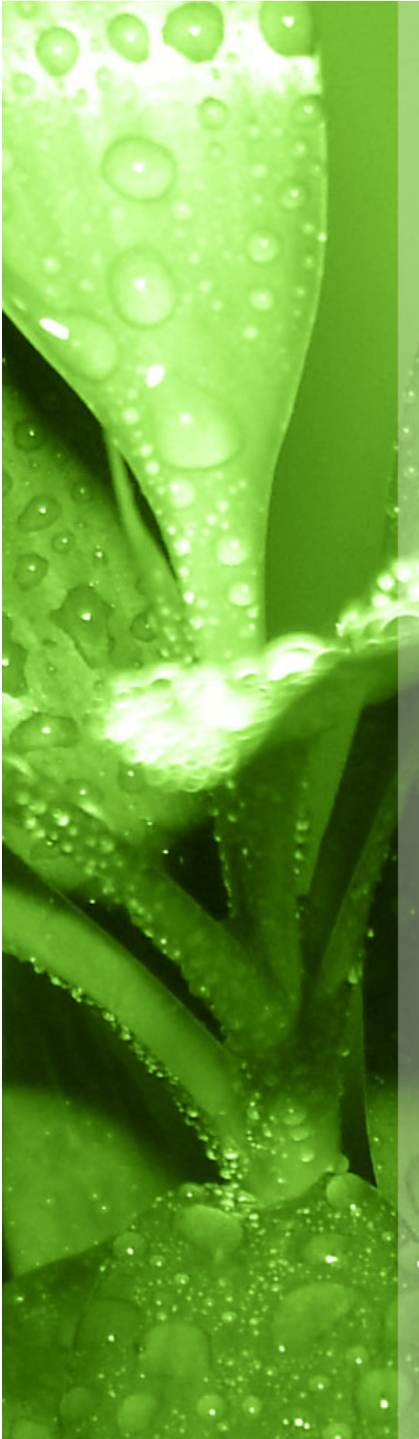
# Trial Design

- Historical/Traditional
- Case Reports/Case Series
- Clinical Trials
  - Placebo Controlled?
  - Double Blind?
  - Randomized?
- Why is this important?



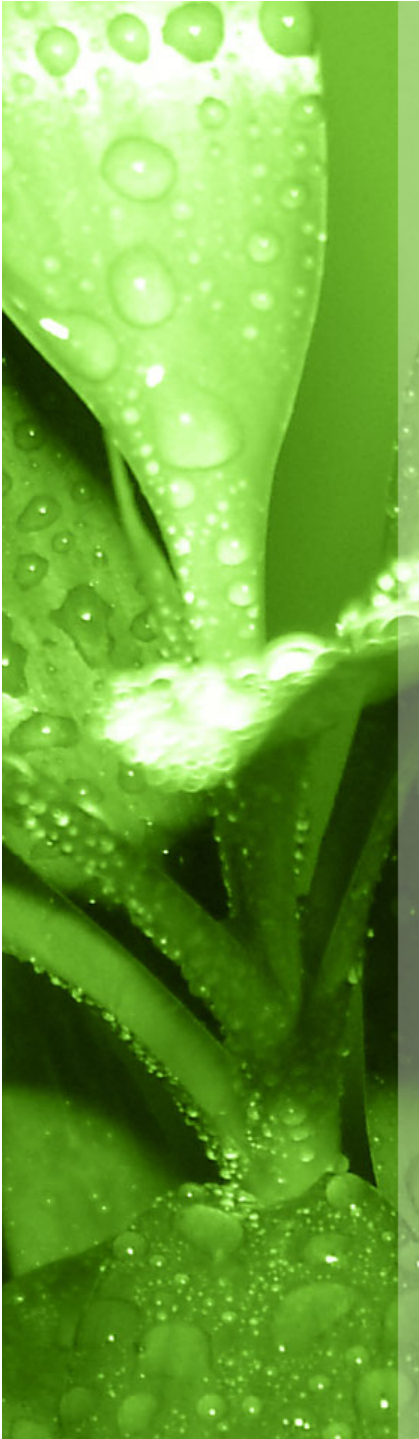
# Trial Design





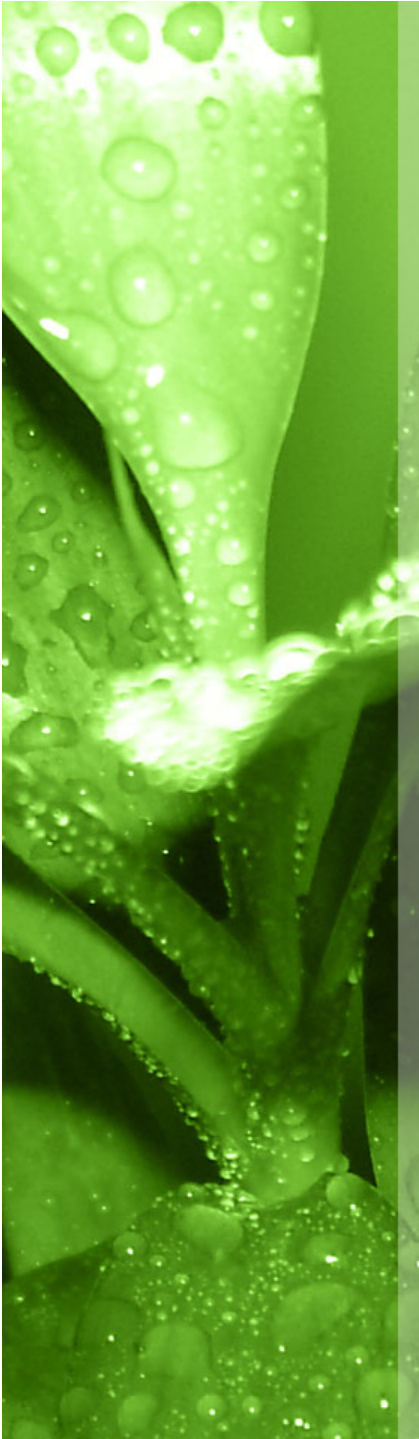
# Natural Products and Cancer

- Claims
  - Prevent cancer
  - Help body fight cancer
  - Help with Adverse effects
  - Cure Cancer



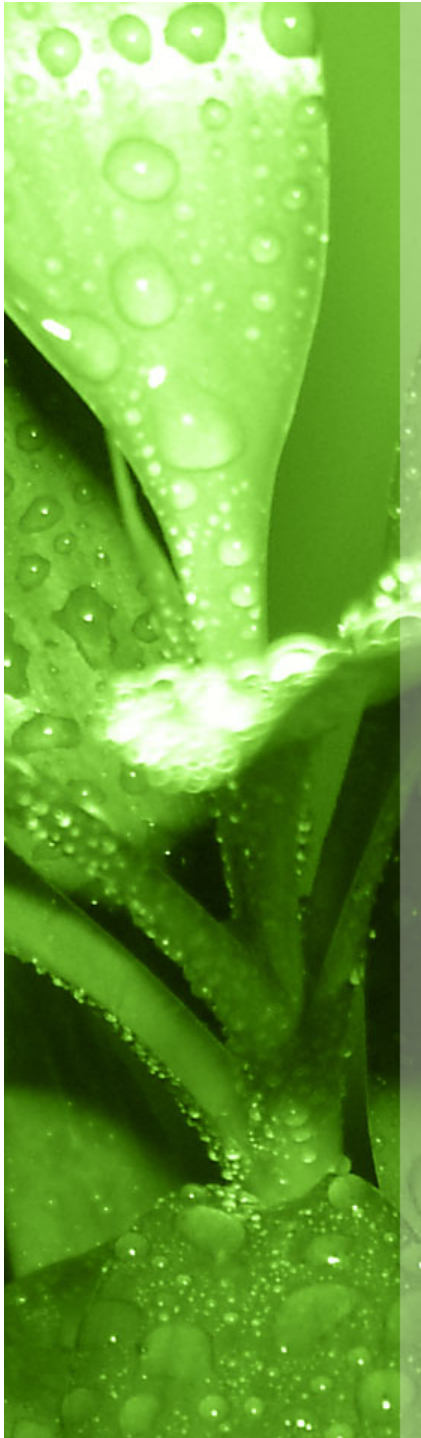
## Are NHP's Right for you?

- ❑ Safe to take?
- ❑ Evidence it will help?
- ❑ Can I afford it?
- ❑ How will I monitor if it's working or causing side effects?
- ❑ Weigh Benefits vs risks



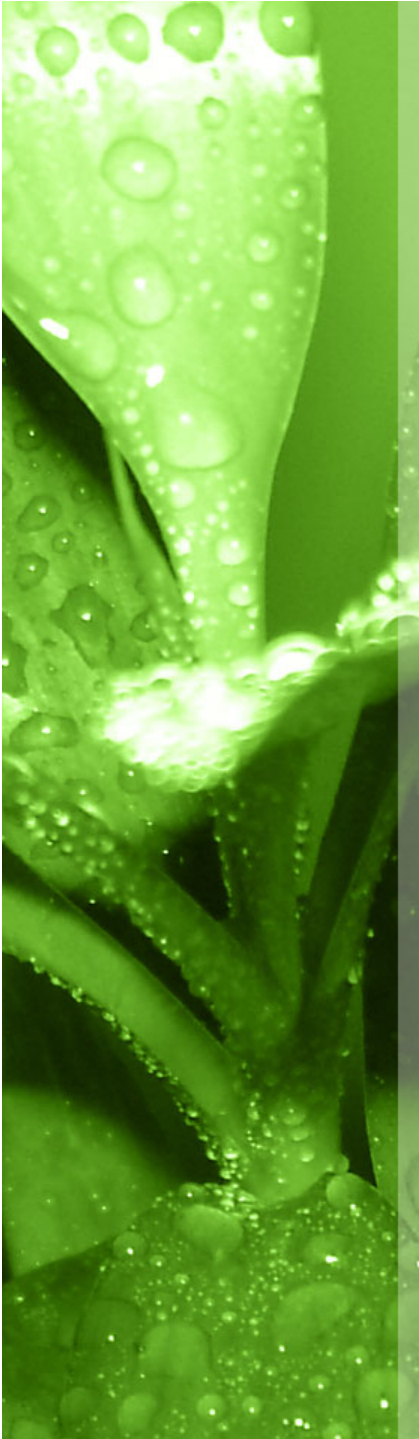
# Safety

- Potential to promote growth of tumors?
- Interact with Standard therapy?
- Interact with other drugs?
- Cause Side Effects/Toxicity?
- Does it have an NPN?



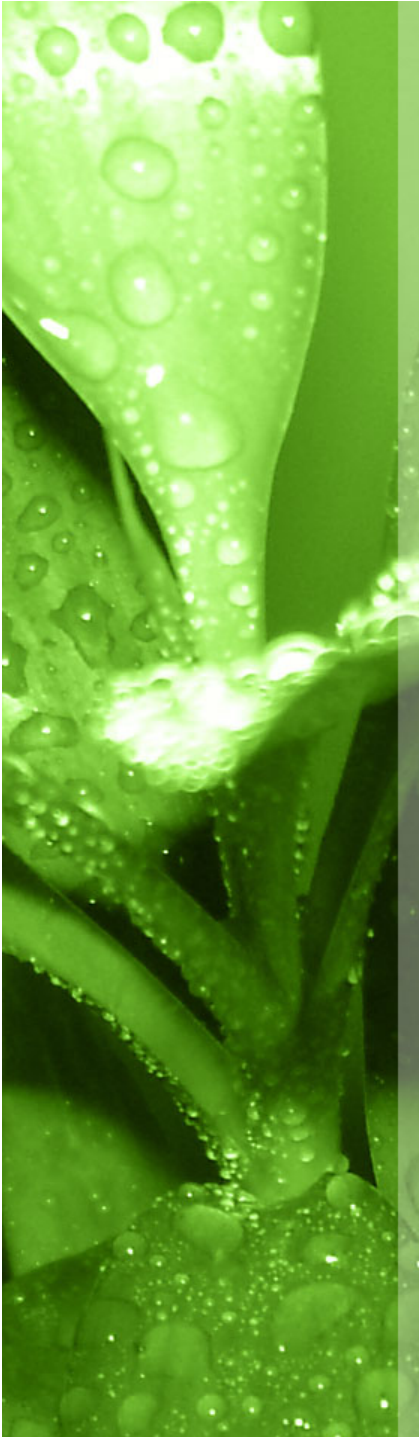
# Efficacy

- What type of studies have been done?
  - ▣ Reasonable number of patients
  - ▣ Controlled conditions
  - ▣ Ask for copies of trials (done in humans!)
- If no studies:
  - ▣ Who is making claims for this product?
- Has the NHP been harvested correctly?
- Is the amount in the product enough to be beneficial? (NPN)



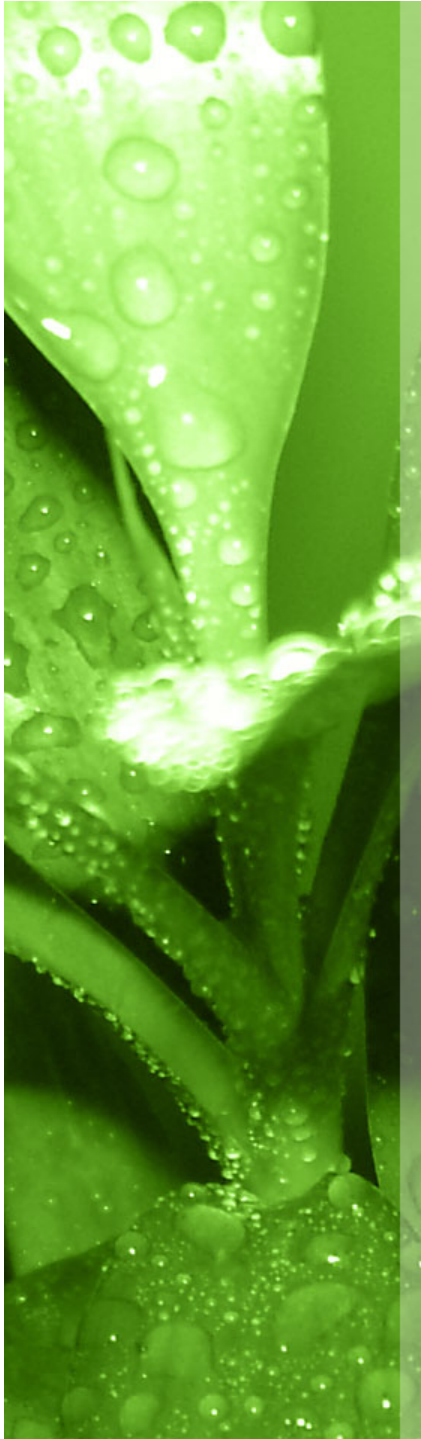
# Benefit versus Risk

- Diagnosis/Current treatment plan
  - What is the response rate for the conventional treatment?
  - Options
    - Early stage treatment versus advanced
- Any known interactions?
- Any known side effects?
- Trials to support NHP benefit?



# Benefit versus Risk

- We don't know if natural products will interact with chemotherapy/radiation (**even if nothing is reported**)
- How long do natural products stay in our system?
  - Is not taking these products for a few days before/after chemotherapy adequate?
- Cost

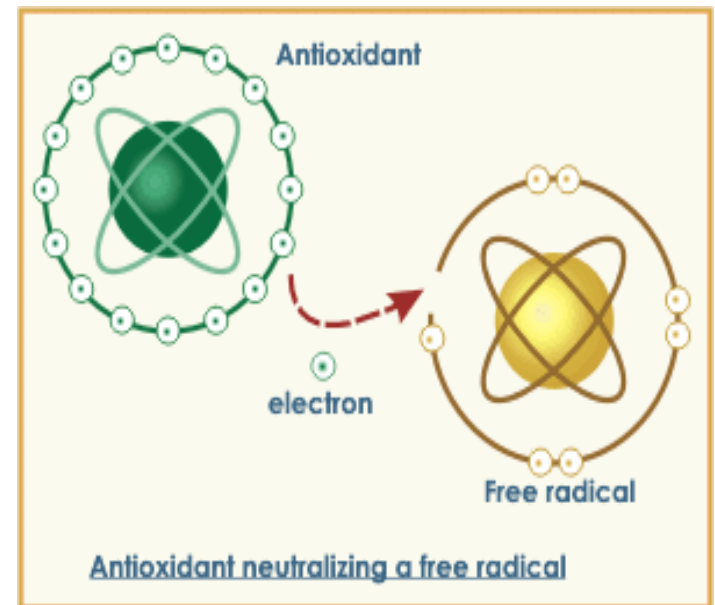
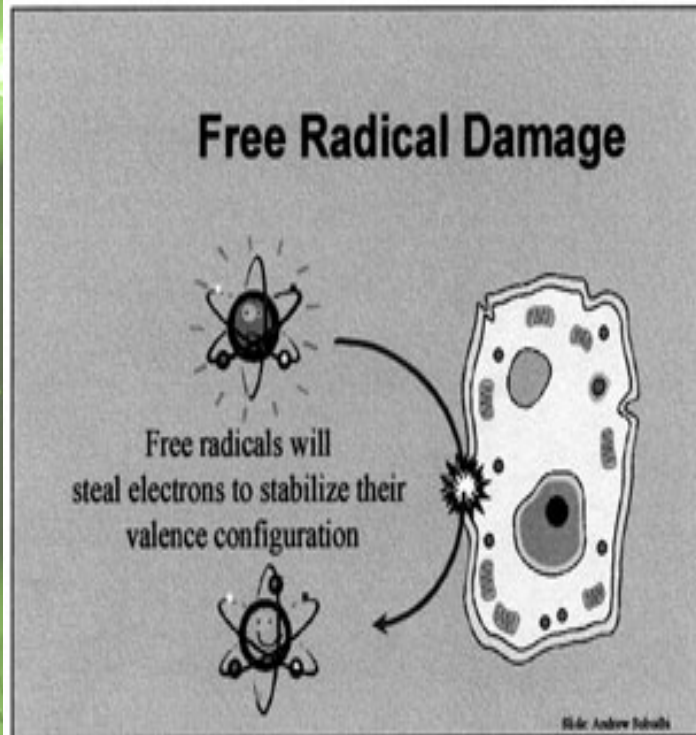


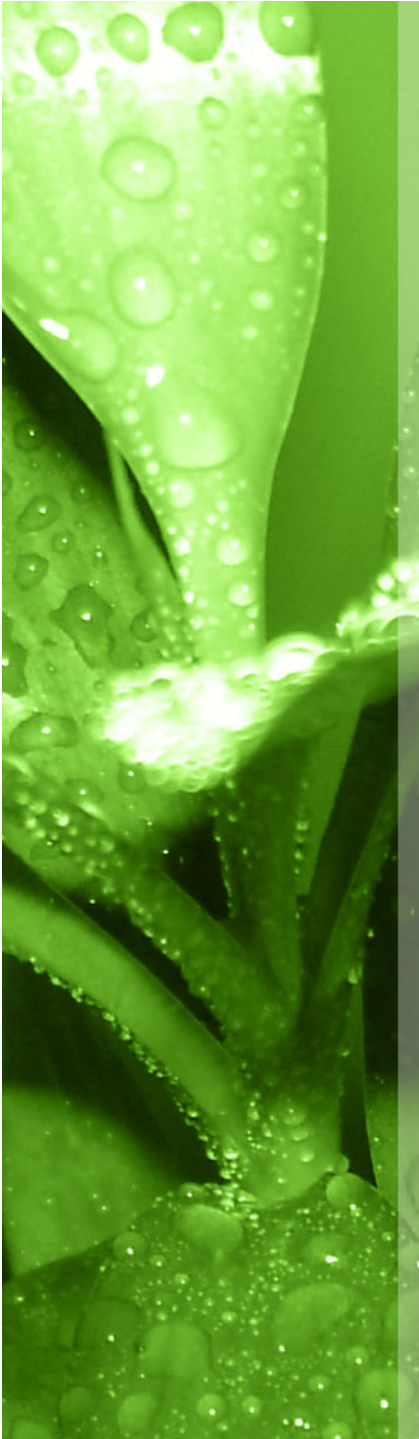
# Potential Drug-NHP interactions in Oncology

- Antioxidants
- Hormonal Activity
- Blood thinning properties
- Liver injury
- Effect breakdown of drugs in the body
- Add side effects or make chemotherapy side effects worse

# Antioxidants

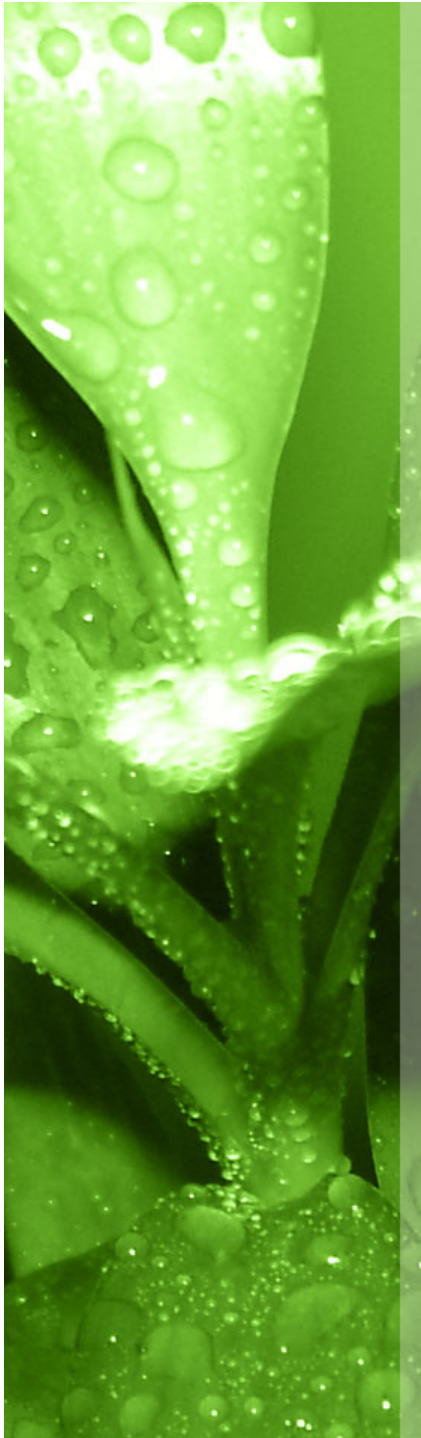
- What is an Antioxidant?





# Antioxidants

- Chemotherapy may act on cancer cells by making free radicals
- Theoretical interaction between these types of chemotherapy and antioxidants
- Must consider
  - How the specific chemotherapy works and how the antioxidant works (not enough research)

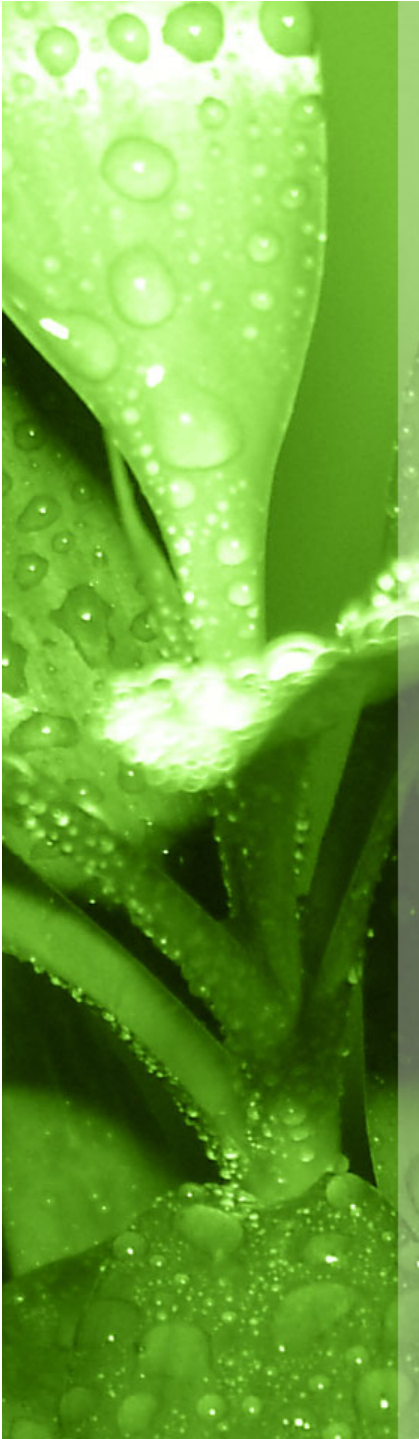


# Chemotherapy Drugs Known To Produce Free Radicals

- **Alkylating agents**
  - cisplatin (Platinol®)
  - carboplatin (Paraplatin®)
  - chlorambucil (Leukeran®)
  - carmustine (BiCNU®)
  - cyclophosphamide (Cytosan®)
  - busulfan (Myleran®)
  - ifosfamide (Ifex®)
- **Anthracyclines**
  - doxorubicin (Adriamycin®, Caelyx®)
  - daunorubicin (Cerubidine®)
  - epirubicin (Pharorubicin®)
  - Mitomycin (Mutamycin®)
  - Bleomycin (Bleoxane®)
- **Podophyllum agents**
  - etoposide (VP-16, Vespid®)
  - teniposide (Vumon®)

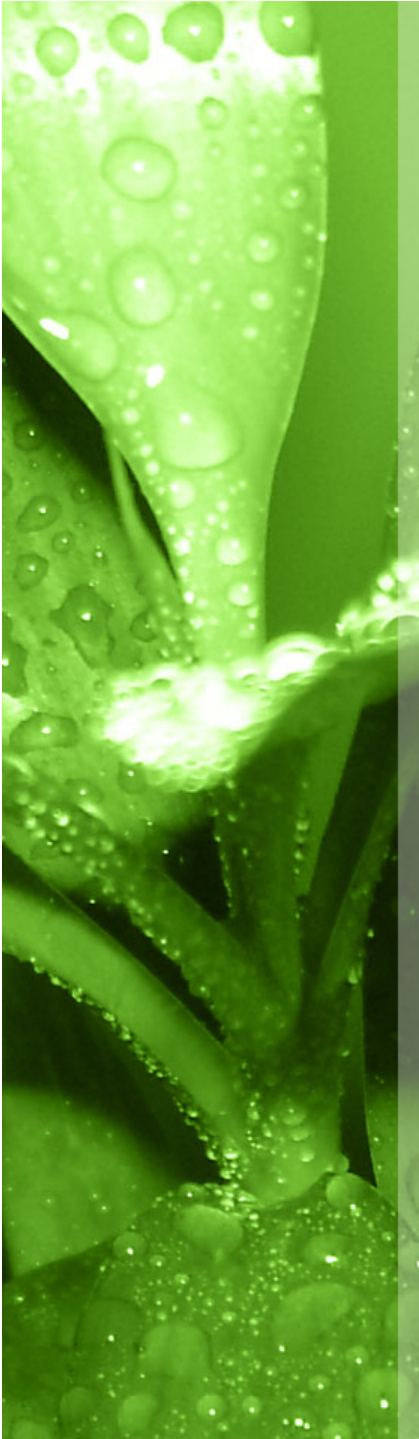
Complementary Medications and Chemotherapy

Sharya Vaughn Bourdet, PharmD and Robert Ignoffo, PharmD, Clinical Professor UCSF



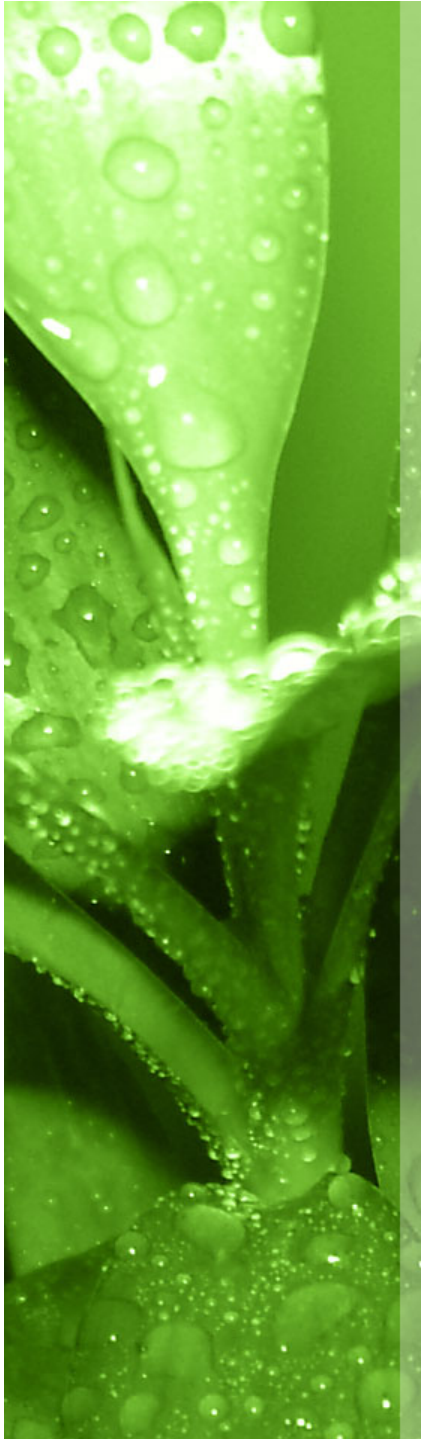
# Antioxidants - Examples

- ❑ Glutathione
- ❑ Vitamin A, C, E
- ❑ Selenium
- ❑ Melatonin
- ❑ N-Acetylcysteine
- ❑ Co-enzyme Q-10
- ❑ Green Tea
- ❑ Grape seed extract



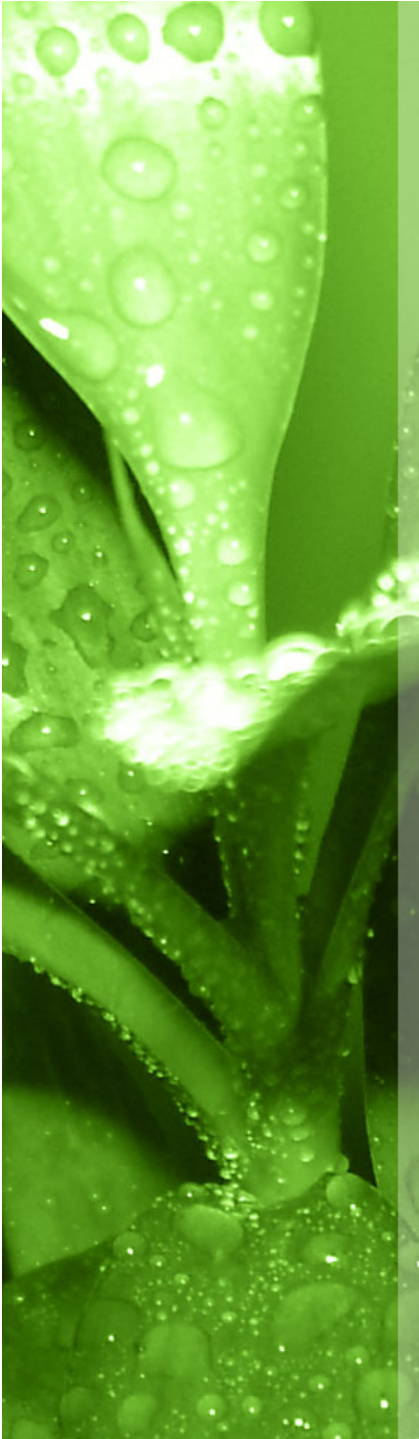
# NHP's & Hormones

- Hormone Sensitive Tumors
  - ▣ Breast
  - ▣ Endometrial
  - ▣ Prostate
- Phytoestrogens – *debate*
- Examples: Black Cohosh, Flaxseed, Ginseng, Milk Thistle, Red Clover, DHEA



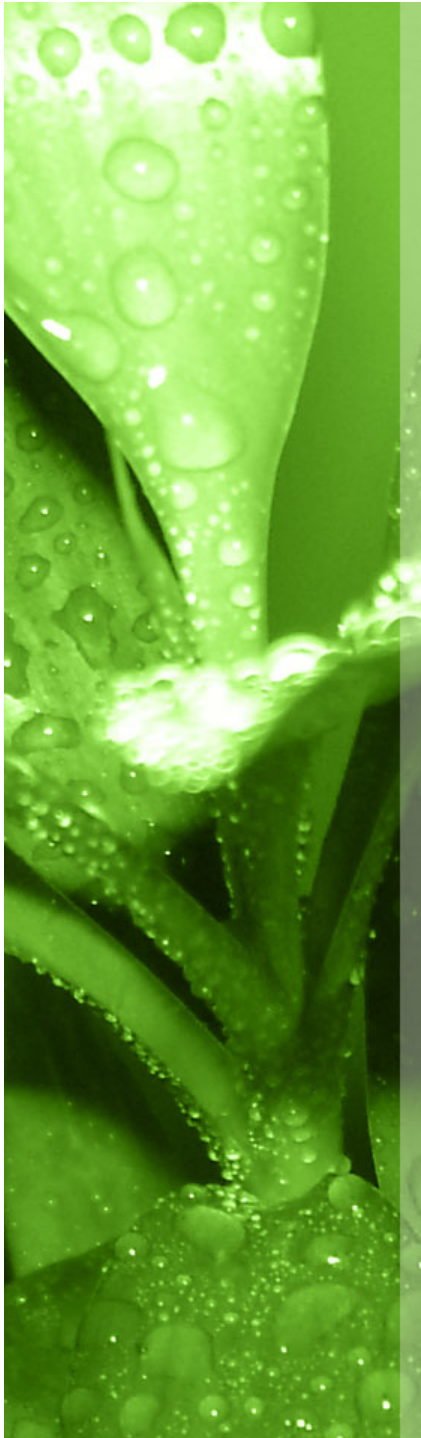
# NHP's with Blood Thinning Properties

- ❑ Chemotherapy can decrease blood clotting “Platelets”
- ❑ Interaction with Warfarin
- ❑ Inadequate monitoring
- ❑ Examples: Alfalfa, Chamomile, Clove, Feverfew, Garlic, Liquorice, Red Clover, Willow



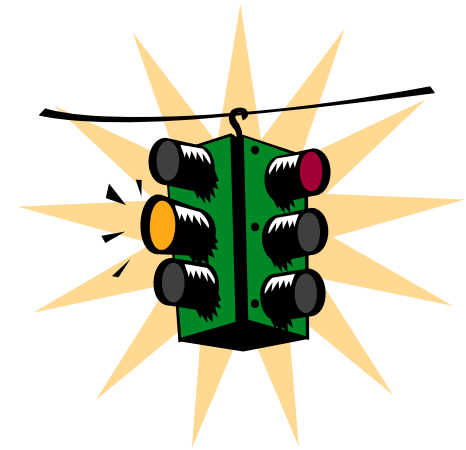
# NHP's that may cause liver injury

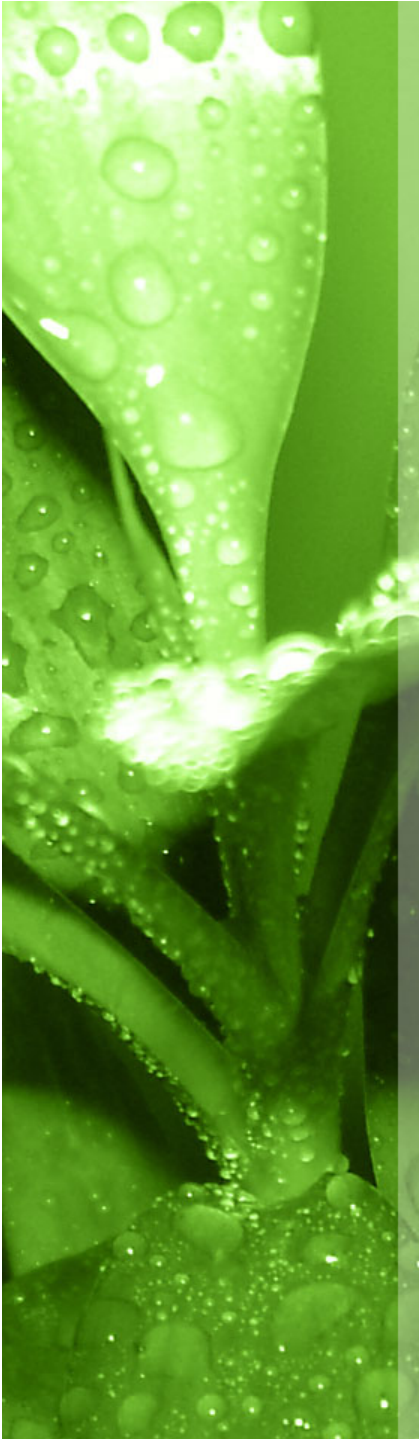
- Liver has many important functions including:
  - Detoxification
  - Digestion
  - Break-down of drugs
- Examples:
  - Kava
  - Mistletoe
  - Skullcap



## NHP's that may effect the breakdown of drugs in the body

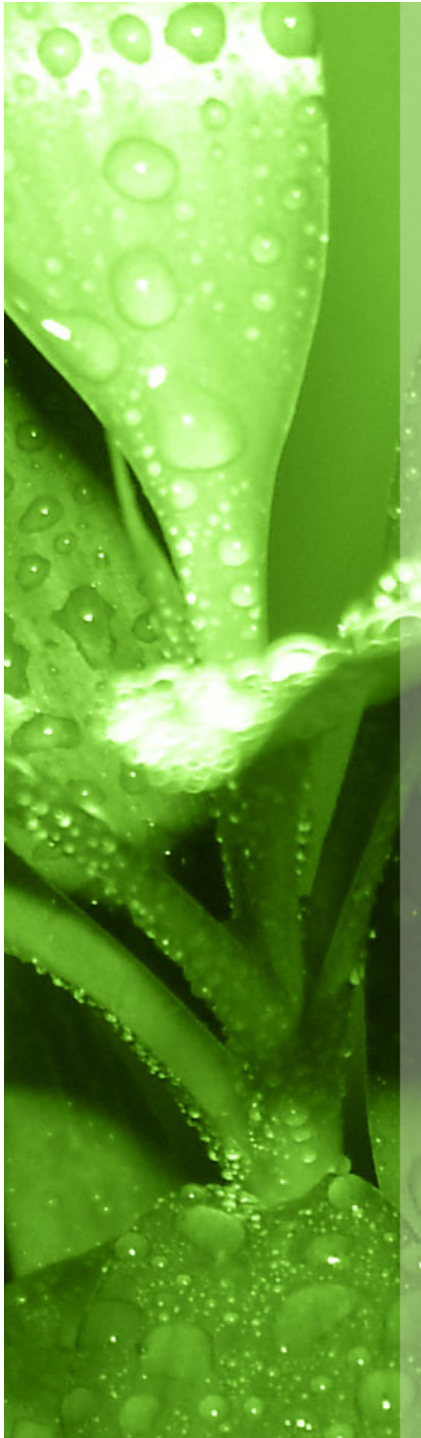
- Liver 'Traffic Jam'
  - ▣ Competing
  - ▣ Speeding up
  - ▣ Slowing down
- Examples: St. John's Wort, **Grape Fruit**, Milk Thistle, Panax Ginseng, Ginkgo Biloba





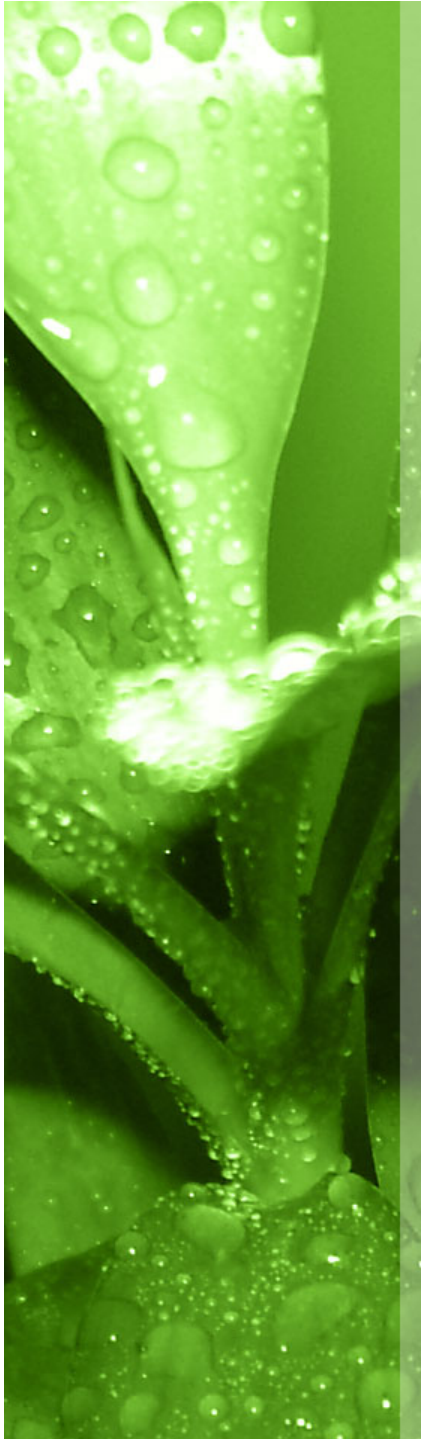
## Add side effects or make chemotherapy side effects worse

- ❑ Bowel/Bladder Function may be affected
- ❑ May increase nausea/vomiting
- ❑ Increase Fatigue
- ❑ Affect blood counts
- ❑ Cause allergic reactions



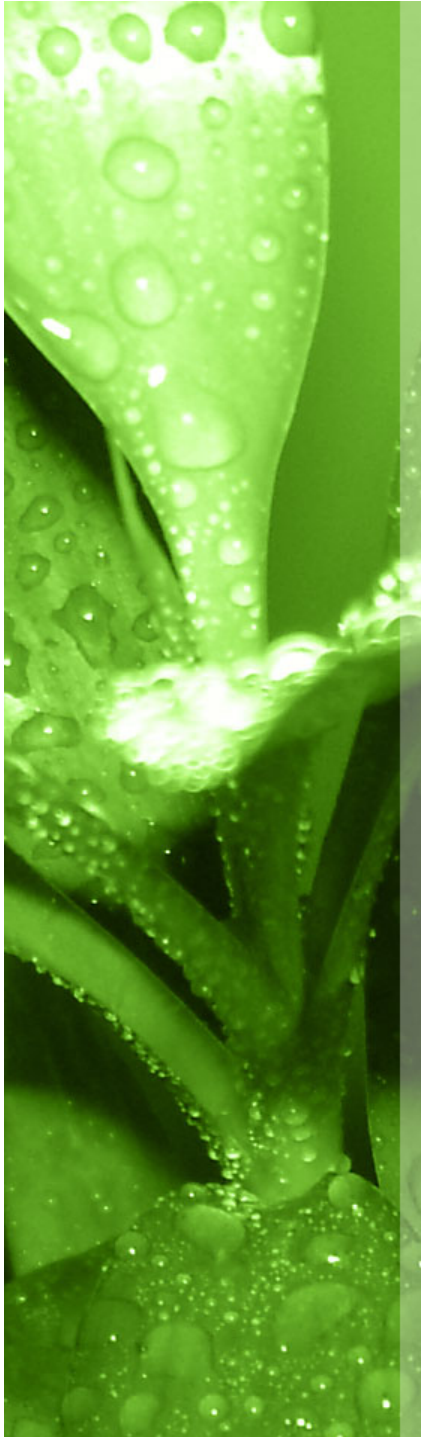
## Where to find Information

- CAMline ([www.camline.ca](http://www.camline.ca))
- Health Canada - Single ingredient monographs for NHPs
- Herb Med ([www.herbmed.org](http://www.herbmed.org))
- **Memorial Sloan-Kettering Cancer Centre** ([www.mskcc.org/mskcc](http://www.mskcc.org/mskcc))
- BC Cancer Agency
- National Center for Complementary and Alternative Medicine  
(<http://nccam.nih.gov/health/atoz.htm>)



## Where to find Information

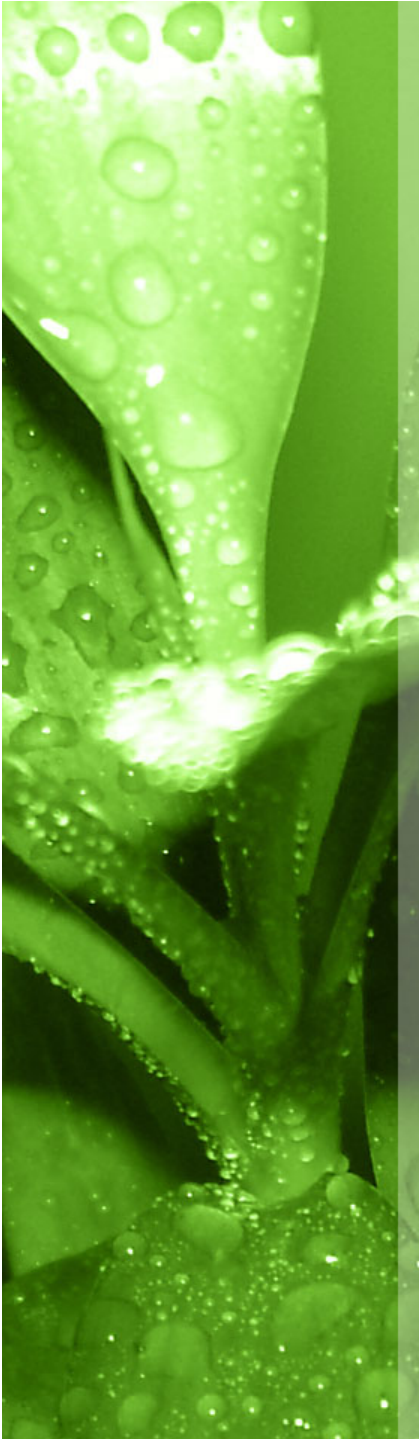
- ❑ **Natural Medicines Comprehensive Database \$**
- ❑ **MD Anderson**  
**([www.mdanderson.org/CIMER](http://www.mdanderson.org/CIMER))**
- ❑ **Natural Standard \$**
- ❑ **Quack Watch (Look under “Questionable Products, Services, Theories” – Cancer: Questionable Therapies)**
- ❑ **Community Pharmacist**
- ❑ **Libraries**



# Evaluating Information

- Internet
  - Source (Manufacturer?)
  - Reliability
  - Based on “good evidence”
- Naturopath
  - Qualifications?
  - Provide literature that is from ‘reliable sources’ (request copies of studies done in humans)

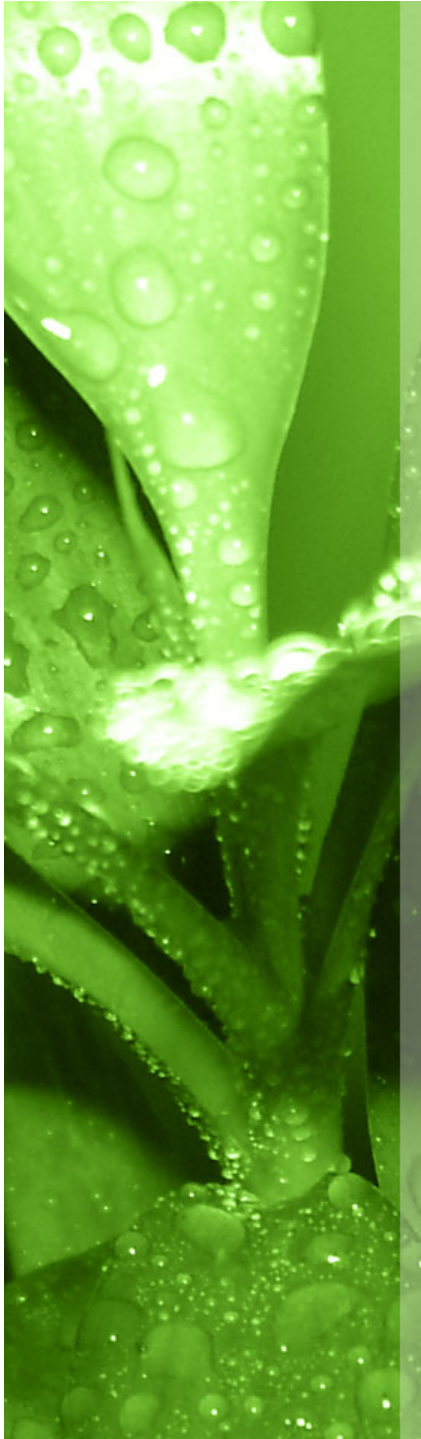
The Annals of Pharmacotherapy 2004 September; Volume 38:  
1406-1411.



## Example #1

PR

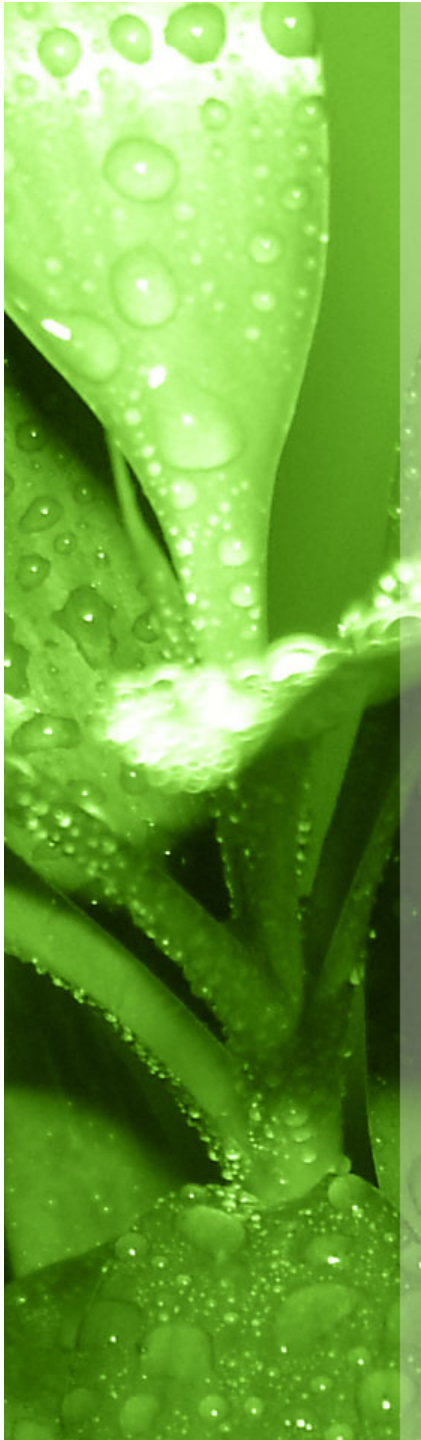
- 42 yo Male with Stage IIIA Non-Small Cell Lung Cancer
- Currently receiving treatment with Vinblastine/Cisplatin and Radiation
- Has been advised to take: Selenium, Melatonin, Iscador and Vitamin D
- What approach should PR take in deciding whether he should take these products?



## Example #1

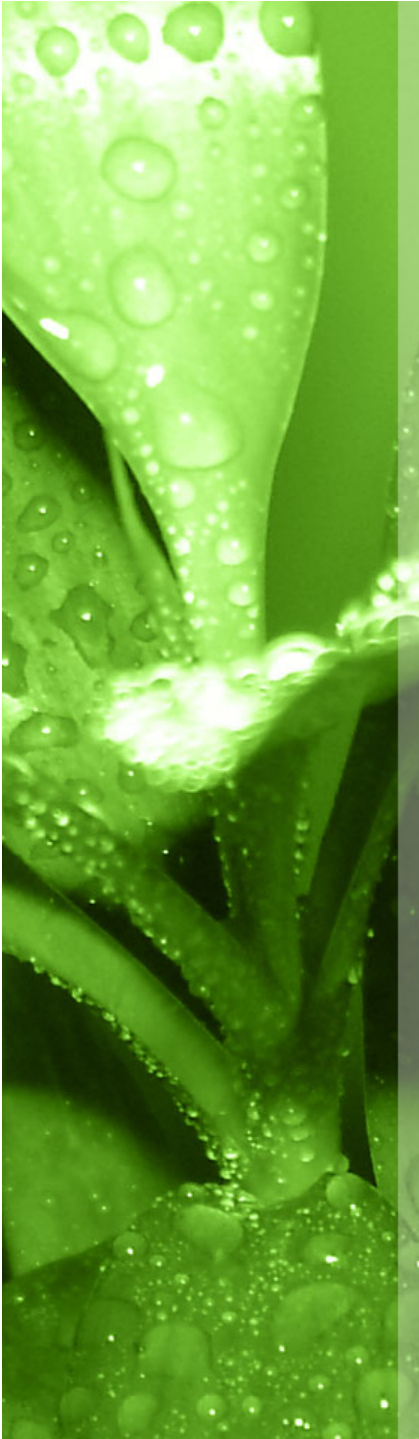
PR

- Check at least 2 separate, reliable, references
- Selenium and Melatonin are antioxidants and should be avoided during active treatment with Cisplatin and Radiation
- Vitamin D: Studies suggest may decrease cancer risk 800-1000IU/day plus Calcium (at least 1200mg/day)
- Vitamins: more is not always better (or safe!)



## Iscador: Benefit vs Risk For PR

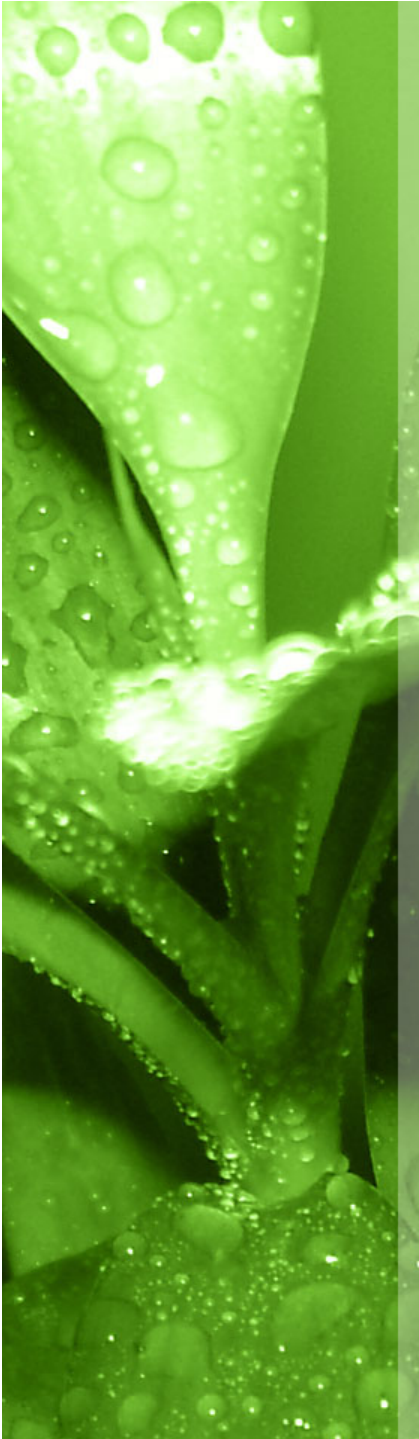
- Data only from small trials (uncontrolled or flawed design) and case reports - conflicting results
- Small difference between proposed helpful dose and toxic dose
- Significant adverse effects: Chills, fever, headache, slowing of heart rate, allergic reactions, low blood pressure, coma seizures, death
- What if PR had Metastatic disease and already progressed on all of modern medicine options?



## Example #2

## CM

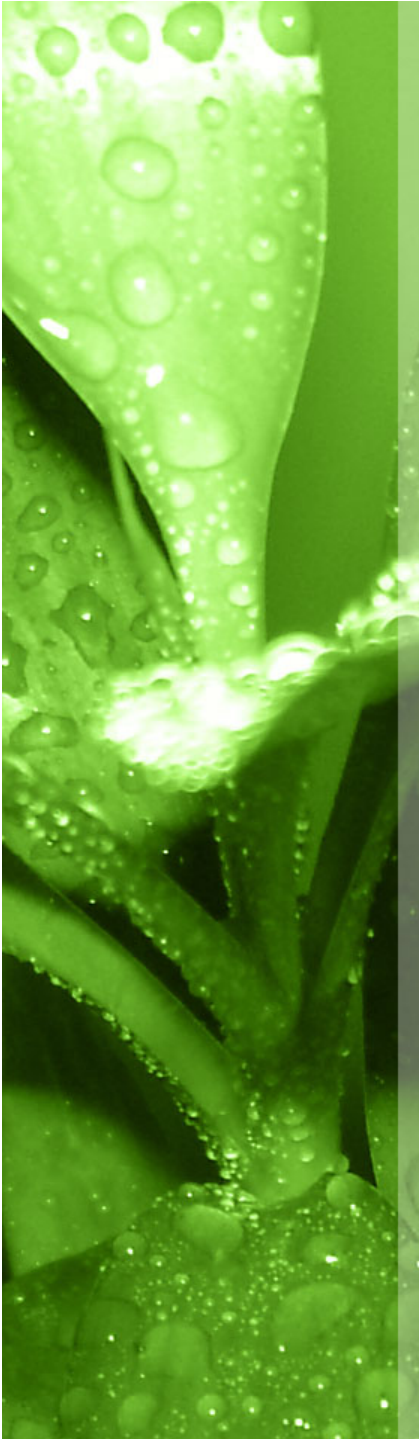
- 62 yo Post-Menopausal Women
- Diagnosed at 58yo with Stage 3 Breast Cancer (Hormone Receptor Positive)
- Mastectomy, Chemotherapy and radiation
- Currently taking Letrozole (Femara<sup>®</sup>)
- No evidence of cancer recurrence



## Example #2

## CM

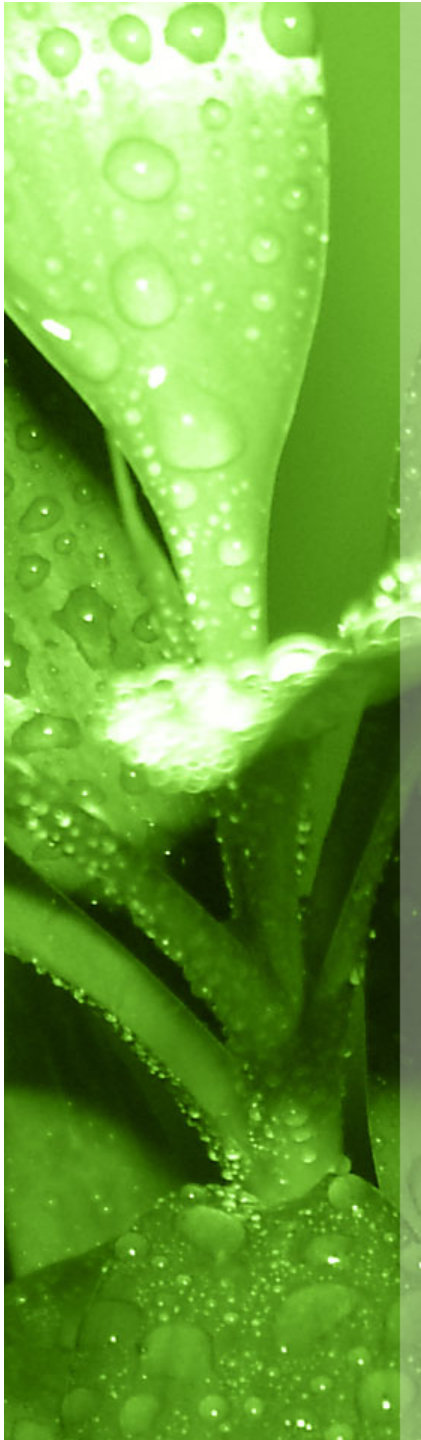
- Her sister has heard that: Soy, Omega-3 and Flax Seed are good for women with Breast cancer and has purchased products from a health food store for her to take.
- CM has also heard from a friend that Melatonin helps prevent Cancer
- What approach should CM take in deciding whether she should take these products?



## Example #2

CM

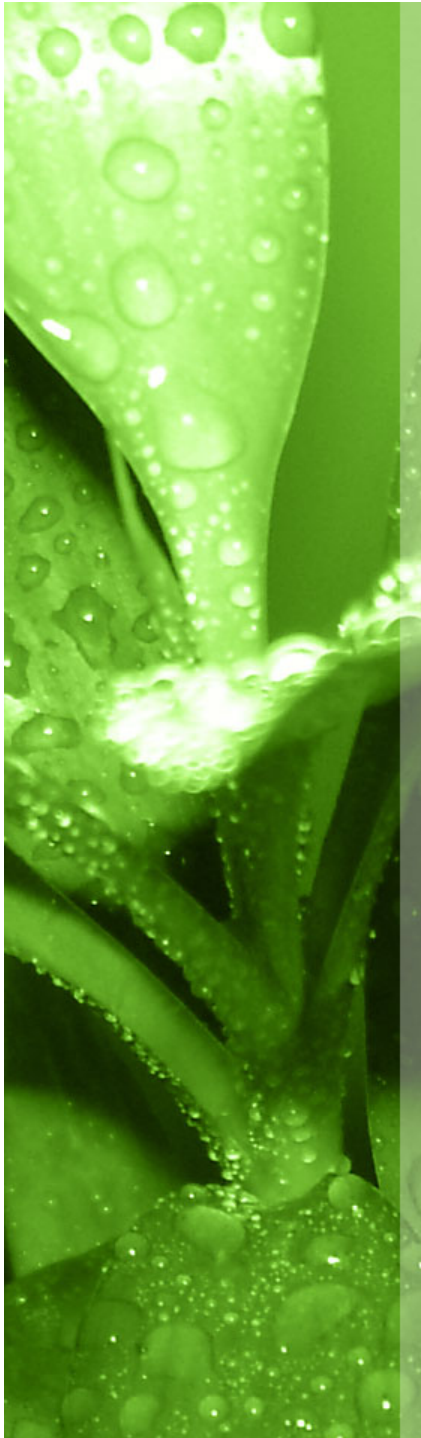
- Check at least 2 separate, reliable, references
- Phytoestrogen debate
  - Soy, Flaxseed (beyond regular diet) may not be a good idea for this patient
  - Omega-3, Melatonin: no absolute contraindication
    - Weigh benefit versus risk



## Example #2

CM

- ❑ **Omega-3** (Alpha-Linolenic Acid)
- ❑ Possibly effective for : Atherosclerosis, Cardiovascular disease, Hypertension
- ❑ Not enough information for other indications
- ❑ May increase Triglycerides and cause weight gain
- ❑ Not advised for patients with Prostate cancer (Family members with increased risk would have to avoid)



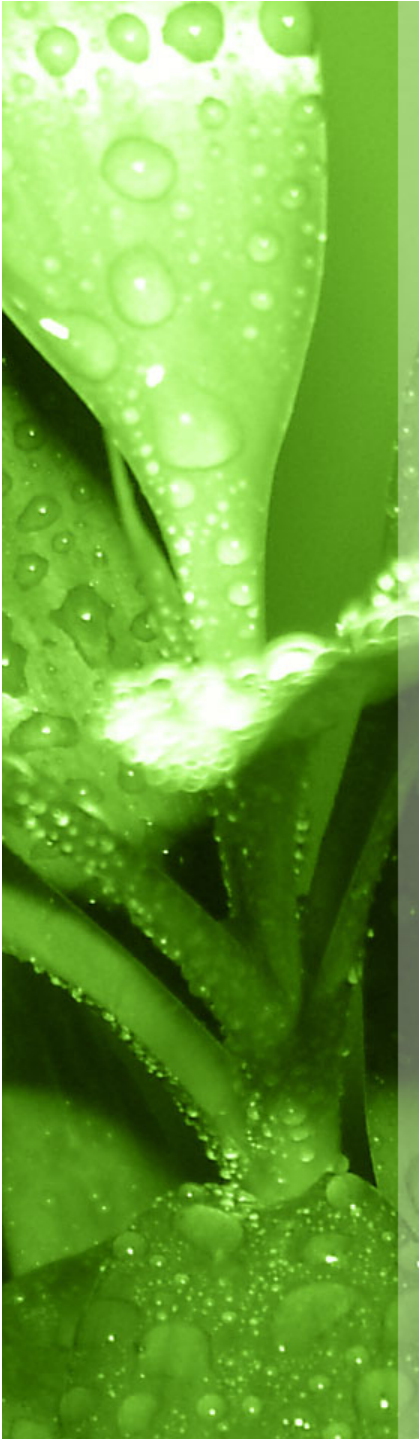
## Melatonin: Benefit vs Risk for CM

### Benefits

- **Possibly** effective for insomnia
- **Possible** effect on solid tumors (needs more evidence)
- Preliminary evidence suggests: **may** inhibit breast cancer cells, **possibly** decrease the # and activity of estrogen receptors (more **human** studies needed to confirm)
- Possible Oncostatic effect
- Very potent antioxidant (would not be advised in combination with certain chemotherapy and radiation)

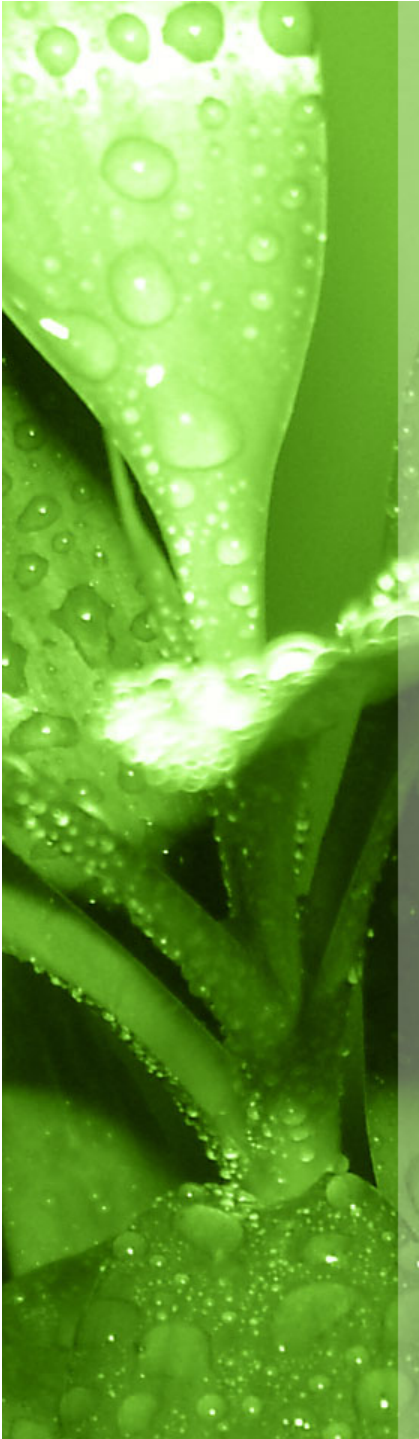
### Risks

- There are reports of products contaminated with toxic ingredients (look for NPN) – make sure not from animal source
- Contraindicated in seizure disorders, depression, diabetes and hypertension
- Adverse effects: Transient depressive symptoms, anxiety, irritability, effect blood pressure, tremor, nausea, vomiting, confusion
- Oncostatic effect – would need to keep taking, long-term use not studied past 9 months
- Unknown Long term adverse effects, **MANY DRUG INTERACTIONS**



## Summary – Questions to ask

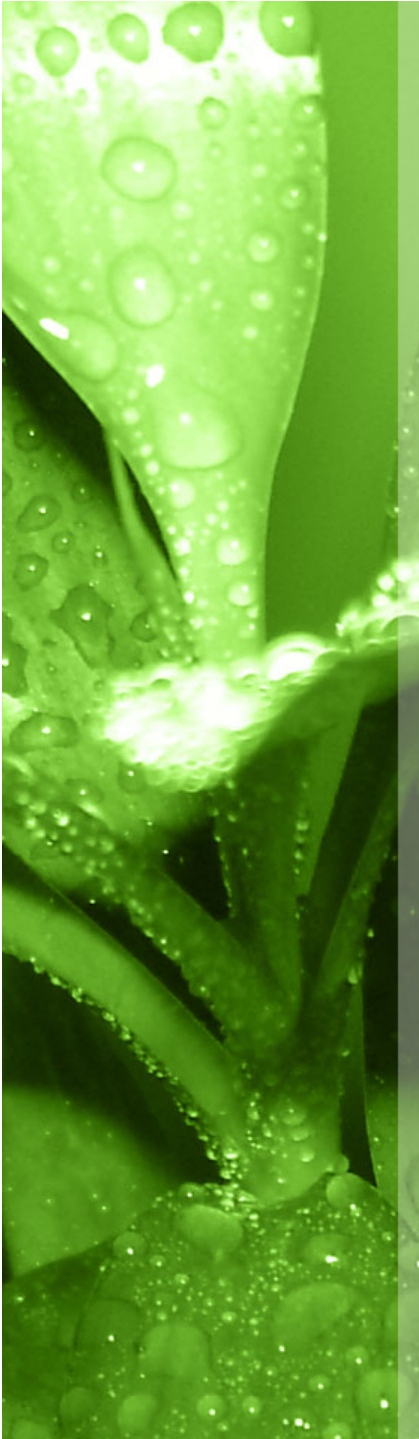
- ❑ Who is suggesting I take this product?
- ❑ Is this product safe for me to take?
- ❑ Will it interact with my medications/cancer?
- ❑ How will it benefit me – what do I expect it to do?
- ❑ Will it cause any side effects?
- ❑ Any evidence it will work?
- ❑ Can I afford it?



# If you decide to try a product

## Develop a monitoring plan

- How will you know if it's working?
- How long do you have to take this product?
- How will you monitor for side effects?
- How will you manage side effects?
  
- Choose a product with an NPN
- Make sure your health care team knows what you are taking!



# Summary

- Gather information from reputable sources
- Make your own decisions (ask for help understanding information if you need it)
- Weigh benefit versus risk
- Do what's best for **YOU**