



uOttawa

L'Université canadienne  
Canada's university

**BSI/ISB**

**Biopharmaceutical Sciences Institute**

**Institut Des Sciences De Biopharmaceutical**

**A New VISTA**



## Innovative

- Consolidating the unique uOttawa Biopharmaceuticals 4yr undergraduate program (550-600students) with the Centre for Research in Biopharmaceuticals.....into a single Institute
- Consolidation is consistent with forecasted trends in R&D and advanced training for bio-medical and biotechnology fields
- Encompasses Chemistry, genomics, pharmacology streams and the plan is to incorporate training/research streams in Pharmacotoxicology and Pharmacovigilance/Risk Assessment



**Public Health / Medical / Industrial / Commercial Needs**

# Our Expertise

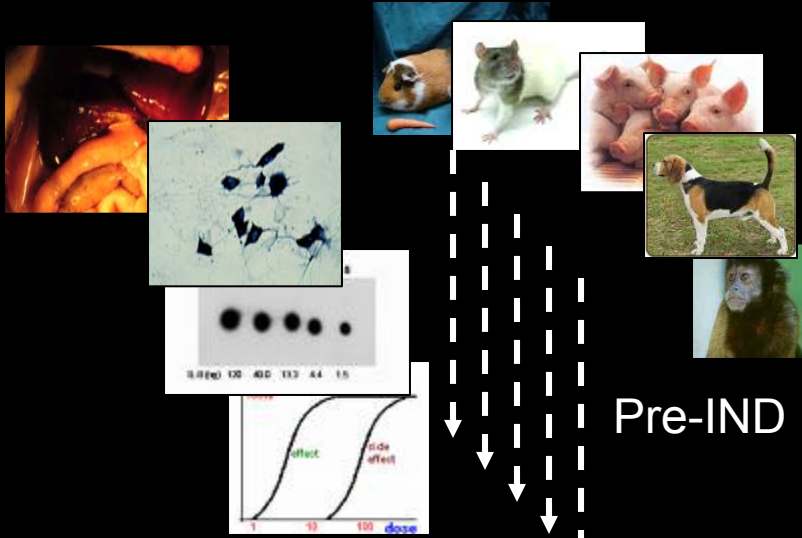
# Your Expertise

## Pharmacotoxicology

## Pharmacovigilance

### Bench

### Bedside



Experimental  
Data base rigor

Pre-IND

Trials Rigor

Clin.  
Trials



Data Base Rigor?

Use of screening algorithms and computer systems to efficiently signal higher-than-expected combinations of drugs and events in the spontaneous reports database.

## Pharmacotoxicology vs Pharmacovigilance

Detecting harmful actions

.....*before* drug approval vs *after* approval

Either way, it all comes down to data quality & quantity. And then there is the stuff of science... *data interpretation!!*

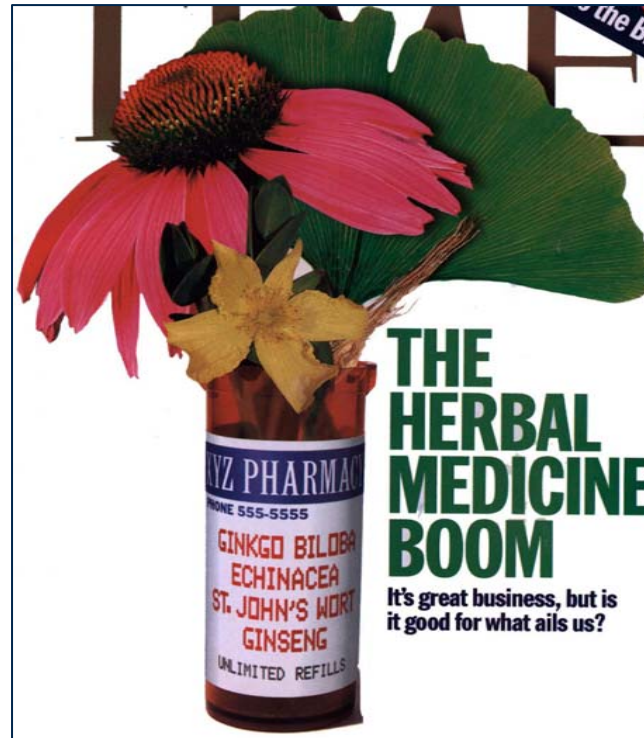
Total number of new **medicines** approved in US during 1990's = 370

49 (13%) were **biopharmaceuticals...**

G. Walsh *Nature Biotechnology* **18**, 831 - 833 (2000)



- **Market value growing 10 - 15% pa**
- **2005:**
  - global ~ 60 bill US\$
  - USA ~ 47 bill US\$
  - UK ~ 1.6 bill UK£
- **US adults:**
  - 49% used a NHP within the past 12 months
  - 24% use NHP regularly



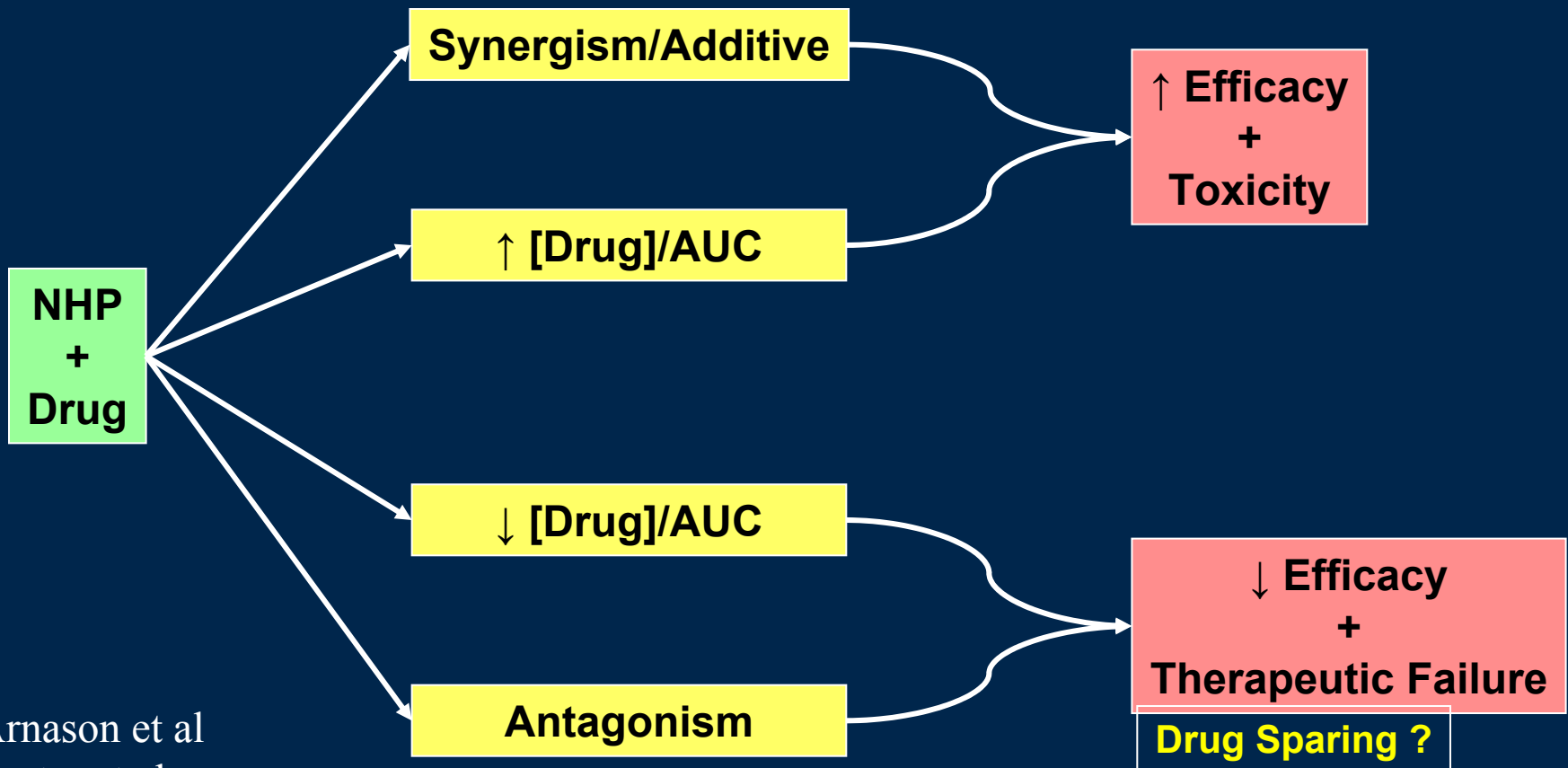
*BPS 4123- J Budinski*

Approx. 1500 botanicals sold as dietary supplements or traditional medicines, herbal formulations ....but are NOT SUBJECT TO FDA pre-market testing for safety

*Env. Health Pers. 106: A590-592 (1998)*



## Clinical significance NHP-Drug Interactions



Arnason et al  
Foster et al

# Mechanism-Based Toxicology and Risk Assessment

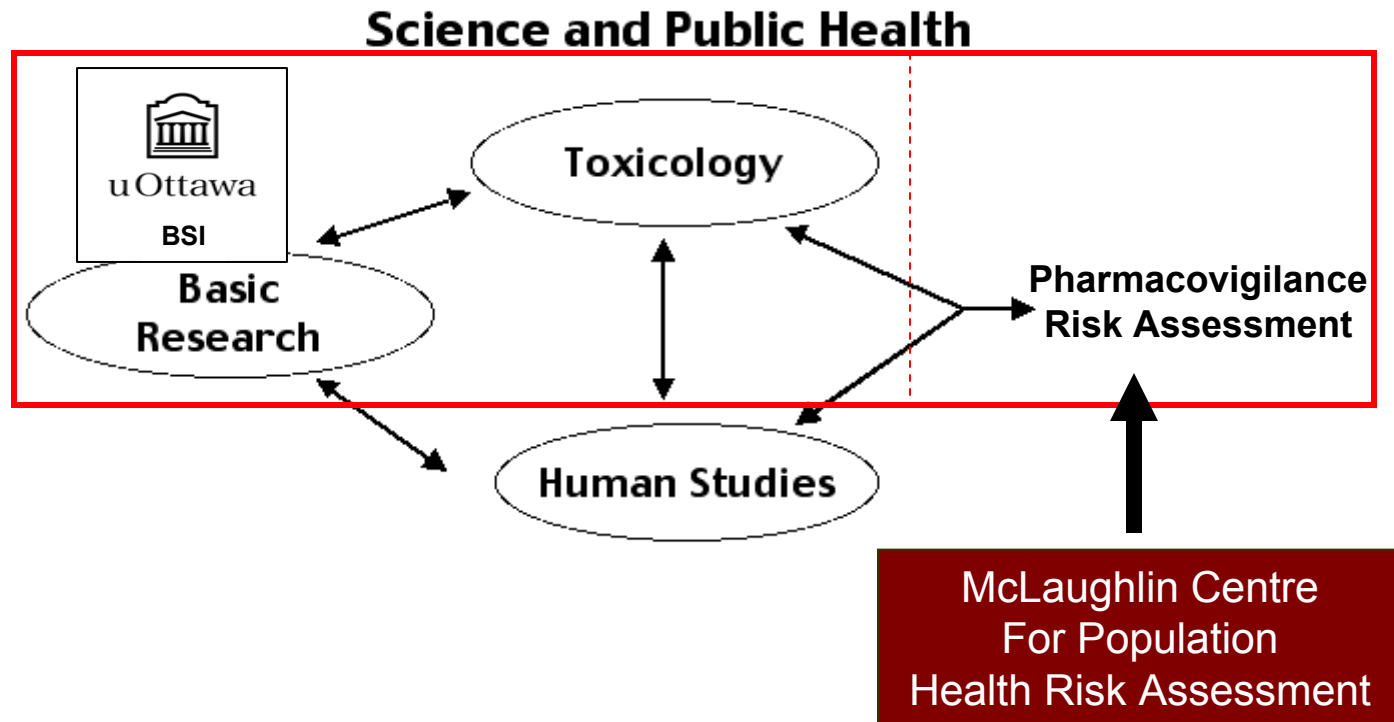
Employing Molecular/biological tools to characterize a chemical's or NHP toxic effect and hence obtain information useful in assessing human risk

## Includes

- identification of receptor-mediated toxicants
- molecular screening strategies
- use of transgenic animal models and complementary *in vivo* tests with rodent bioassays

A long term goal is to develop more specific and sensitive tests for use in risk assessment

# Integrating Pharmacovigilance & Risk Assessment Training



# Developing Expertise & Training Opportunities in the BSI

